



**Sterility Assurance & Quality Risk  
Management Conference**

**October  
8<sup>th</sup> & 9<sup>th</sup>**



# **Transforming QRM for Faster Commercialization**

**A Data-Driven Approach for  
Process Design and Risk Assessment**

**Presenter: Sebastian Scheler, Managing Director, Innerspace**

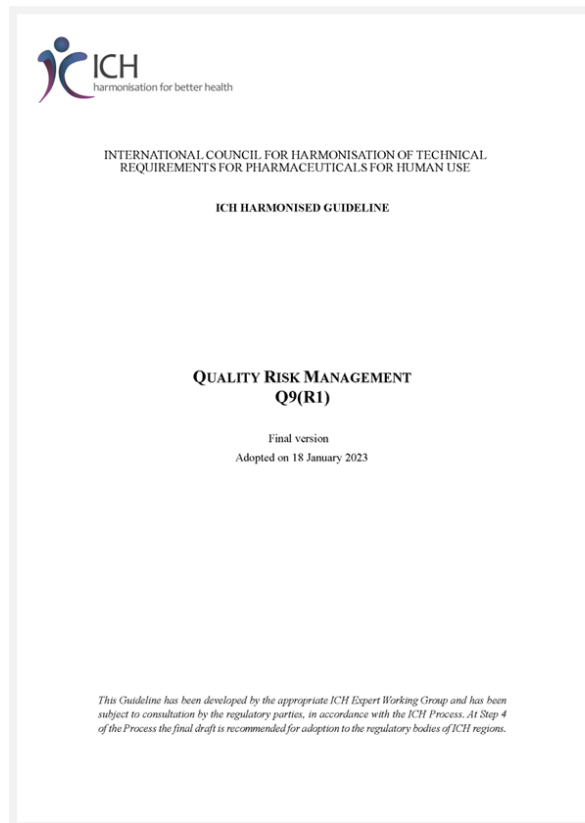
Traditional QRM is  
**(1) highly reliant on manual  
activities and  
(2) remains largely  
unintegrated.**





## ICH Q9 (R1) – Published Guideline Objectives

### Regulatory Requirements for Quality Risk Management (QRM)



There were four areas for improvement identified with the application of QRM:

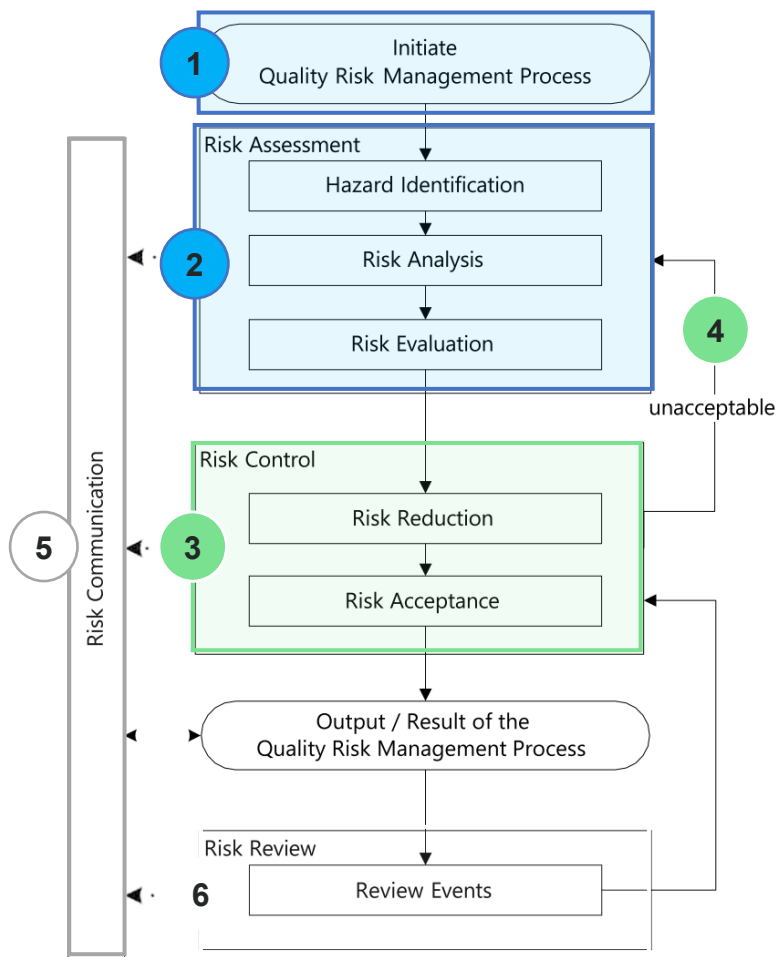
1. **High levels of subjectivity in risk assessments and in QRM outputs.**
2. Failing to adequately manage supply and product availability risks.
3. Lack of understanding as to what constitutes formality in QRM work.
4. **Lack of clarity on risk-based decision-making (RBDM).**

ICH Harmonized Guideline (2023). Guideline Objectives for ICH Q9(R1).  
ICH - International council for harmonisation of technical requirements for pharmaceuticals for human use.



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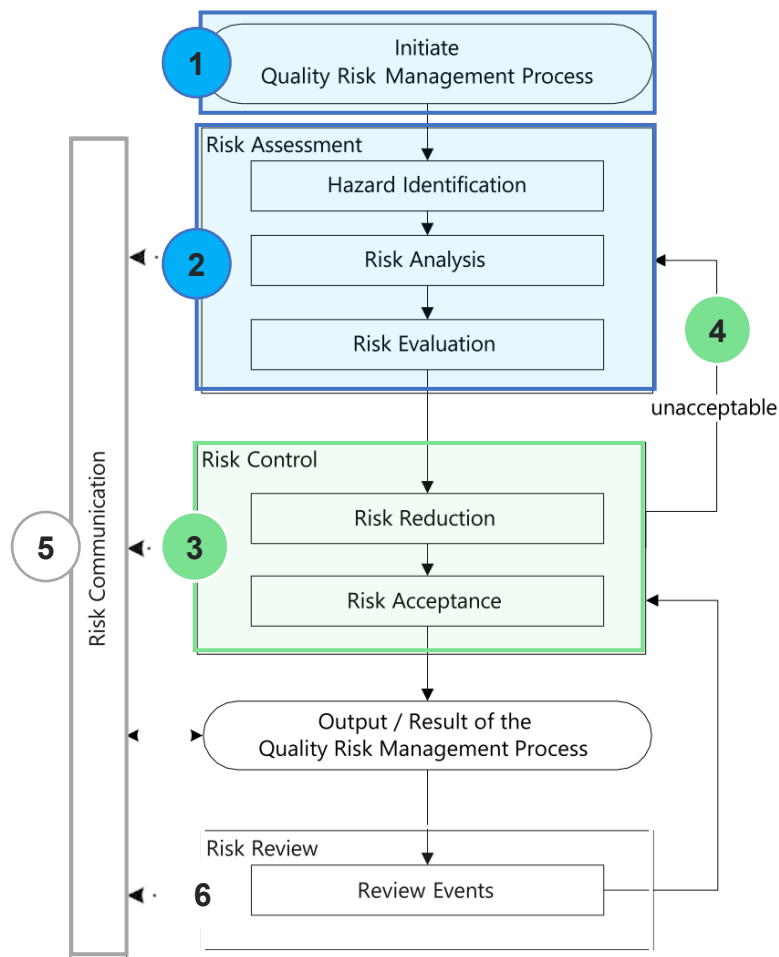


- (1) Process Mapping
- (2) Risk Assessment
- (3) Process Design
- (4) Risk Control
- (5) Risk Communication



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● (1) Process Mapping

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● (2) Risk Assessment

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● (3) Process Design

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● (4) Risk Control



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● (5) Risk Communication



## Traditional Risk Management vs. Frame-by-Frame

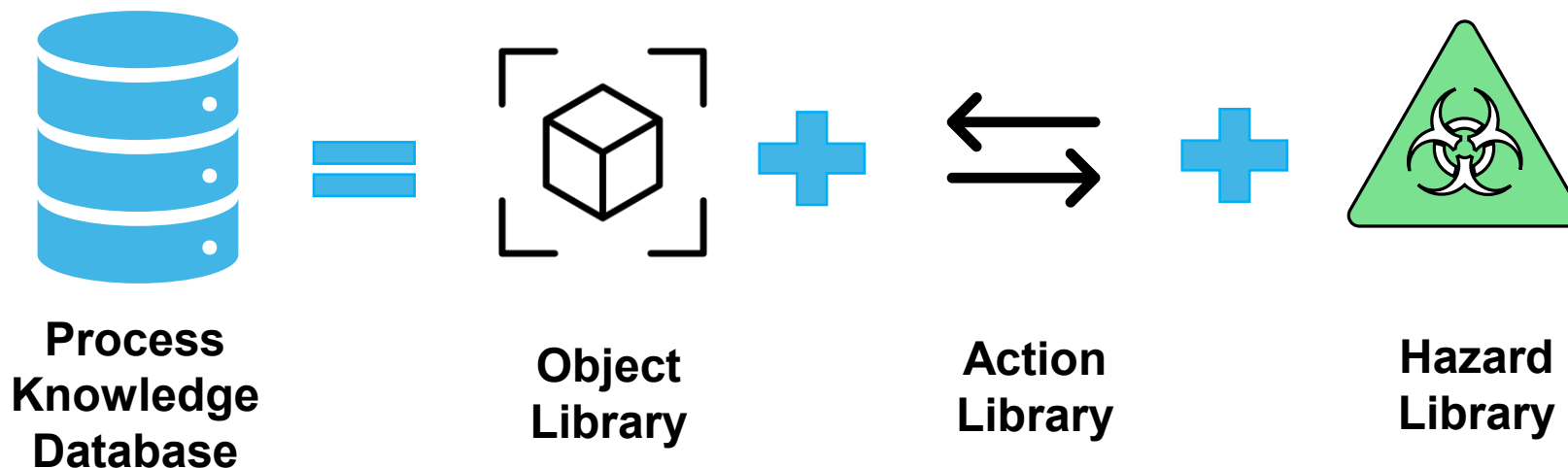
Comparison Chart: Initiate QRM Process

Approach	Initiate QRM Process	
Traditional Risk Management Tools		Manually Created Process Map (e.g., Gemba Walk)
Frame-by-Frame <sup>®</sup>		Digital Process Twin



## The Process Knowledge Database

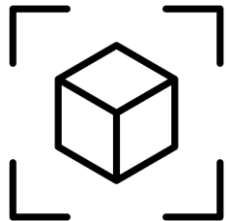
Foundation to create a Digital Process Twin





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Object-Library

## Primary Packaging



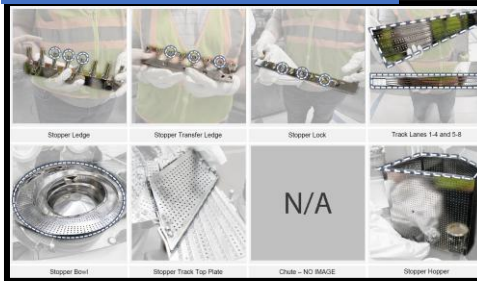
## Monitoring Material



## Equipment Parts



## Etc.



- **Material Properties** – e.g., composition, grade, durability, biocompatibility
- **Dimensions** – e.g., size, length, width, height
- **Geometry** – e.g., shape, form, structural features
- **Weight** – e.g., mass, load, density
- **Surface Characteristics** – e.g., finish, texture, coating



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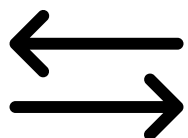
October 8<sup>th</sup> & 9<sup>th</sup>



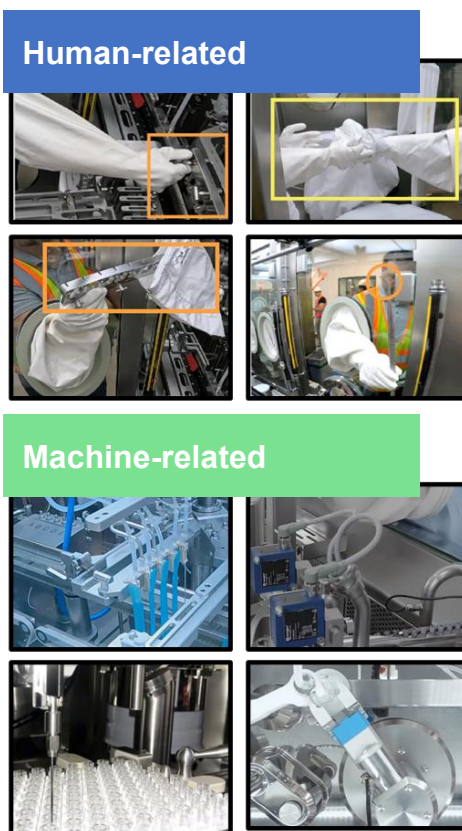
## Library

## Examples

## Technical Specifications



## Action-Library

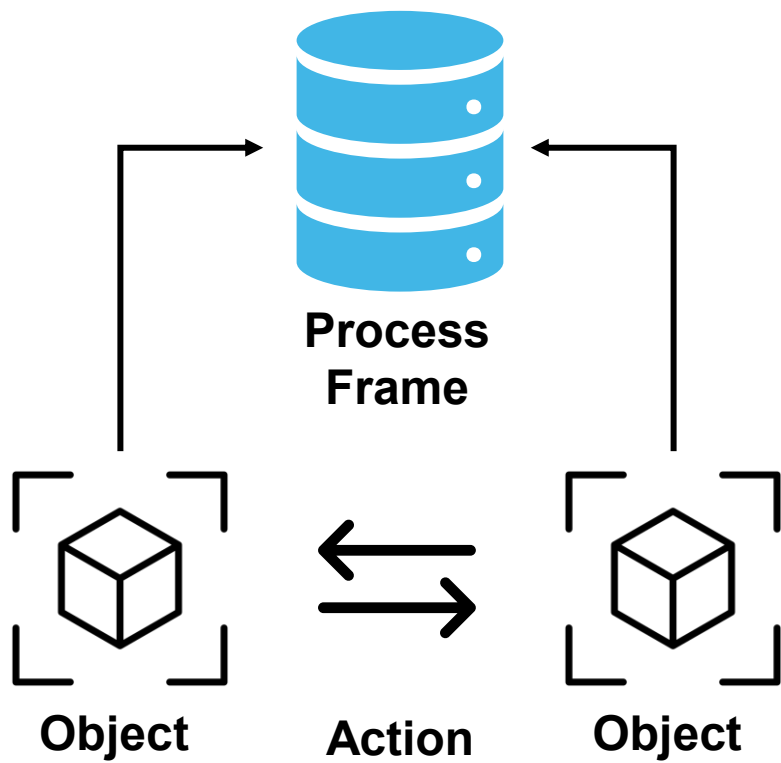


- **Type of Action** – e.g., grab, place, open, close
- **Direction and Orientation** – e.g., upward, rotational, lateral movement
- **Force and Pressure** – e.g., applied force, torque, tension
- **Speed and Timing** – e.g., duration, velocity, sequence
- **Precision and Accuracy** – e.g., alignment, positioning tolerance



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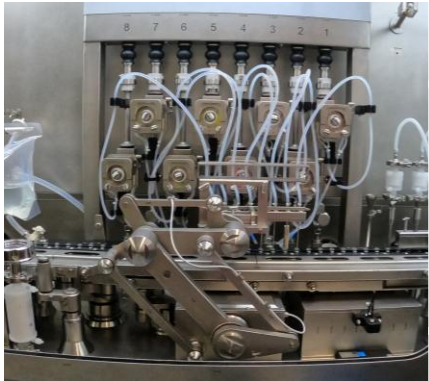
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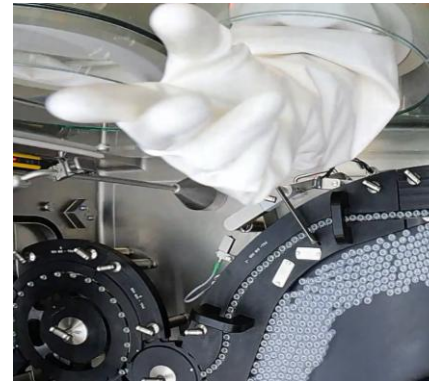


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Frame-Nr.	1025
Description	Insert filling needle in empty vial
Frame-ID	F-FL23-FN-VI-3



Frame-Nr.	0150
Description	Insert right gloved hand in isolator glove
Frame-ID	F-INS-GL-IL-32



Frame-Nr.	1850
Description	Check for proper sterile connection
Frame-ID	F-SC3-FN-VI-3

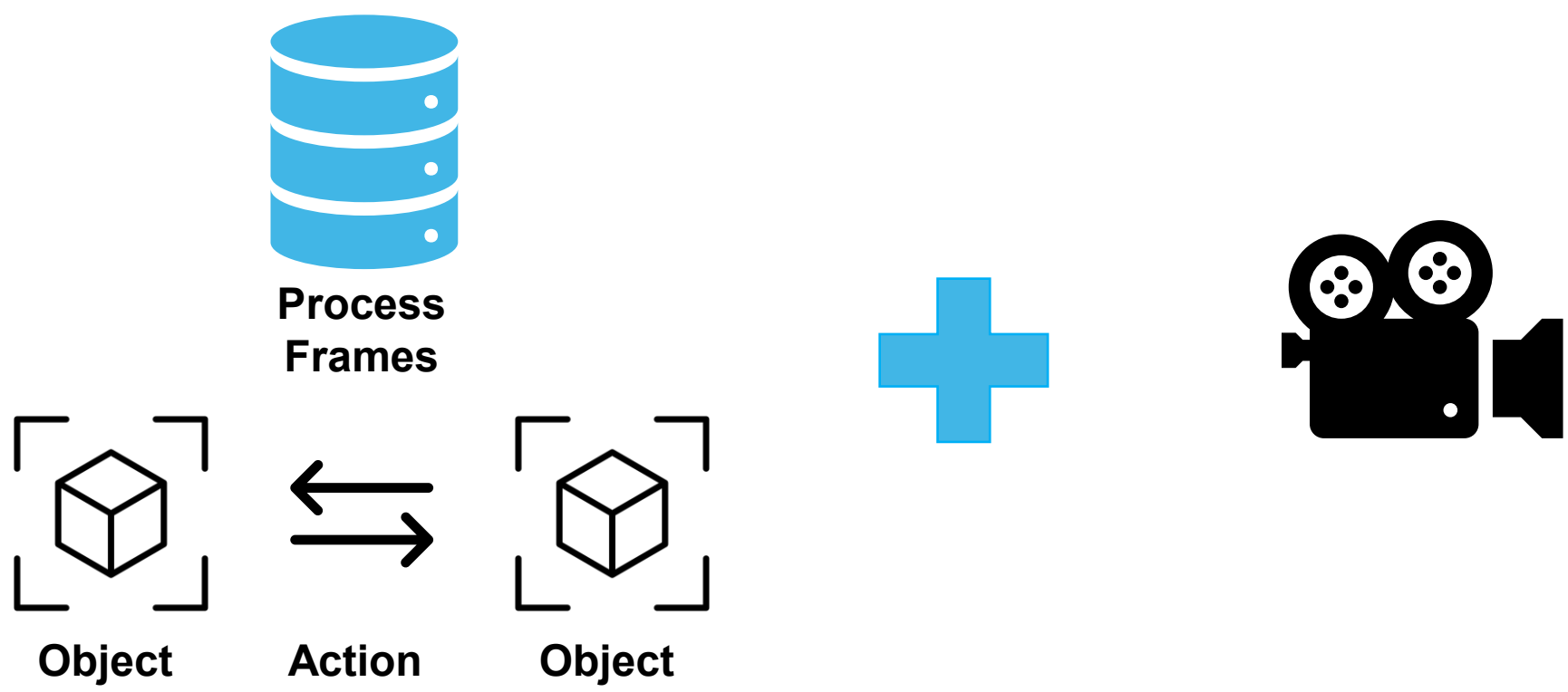


Frame-Nr.	2759
Description	Place covered filling needle in filling needle holder
Frame-ID	F-FL23-PL-VI-NH-1



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Remove vial jam

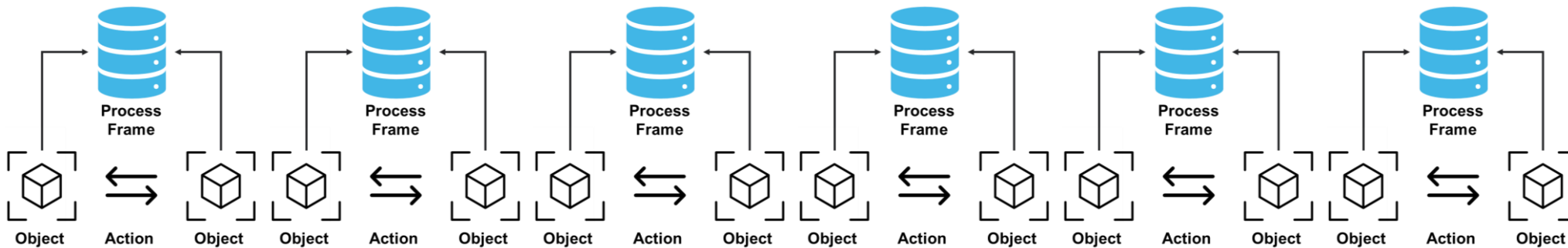


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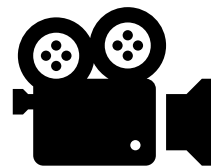
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## Digital Process Twin



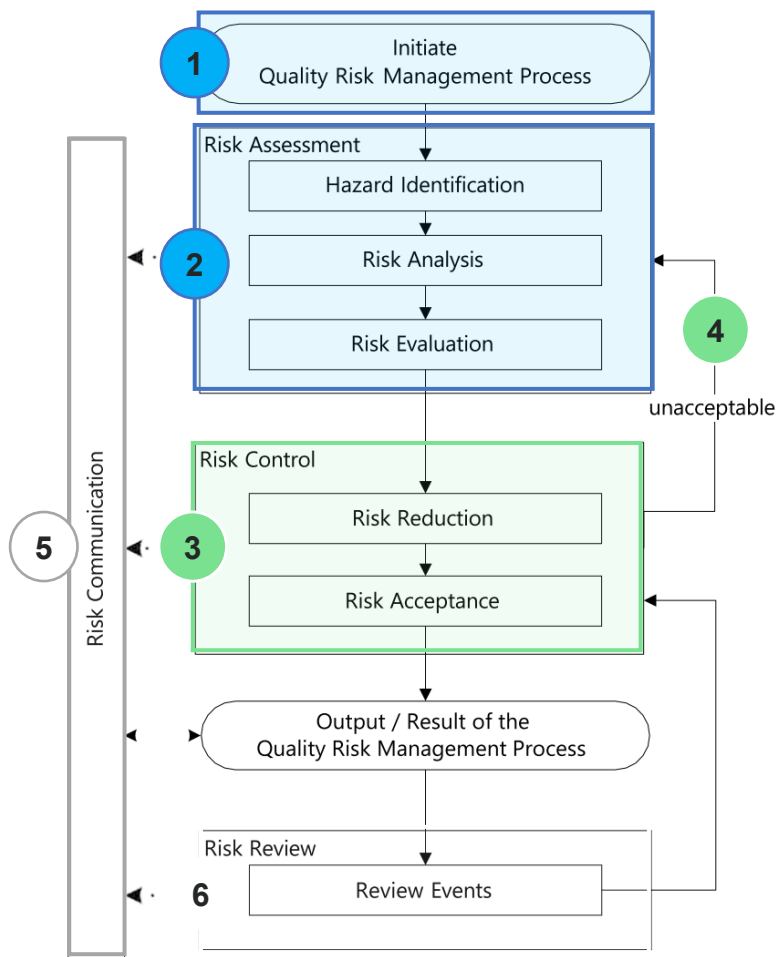
## Videorecorded Process Simulation





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- (1) Process Mapping
- (2) Risk Assessment
- (3) Process Design
- (4) Risk Control
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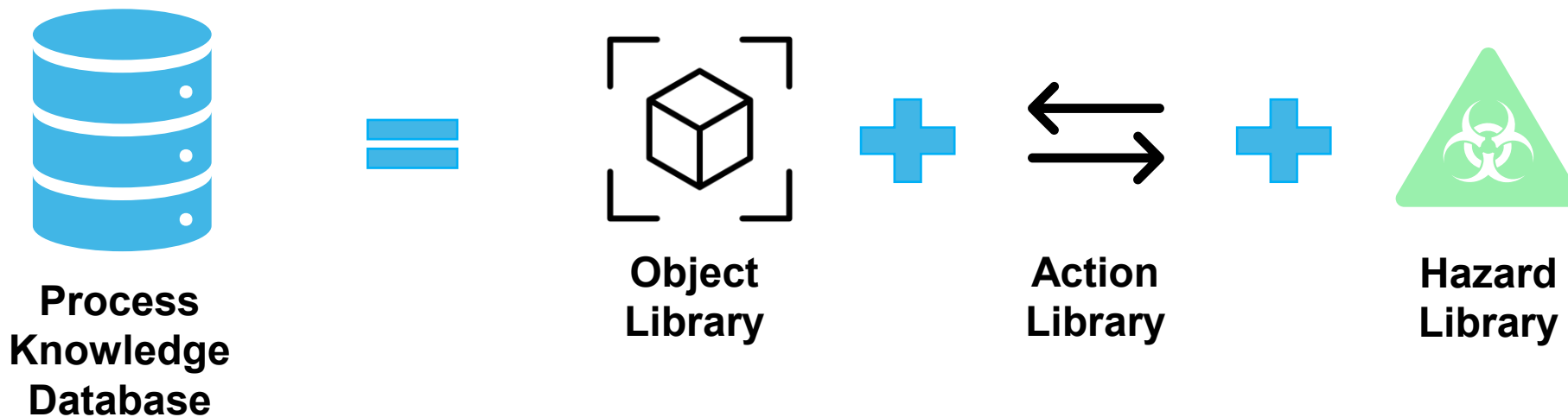
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Approach	Method		Hazard ID	Risk Analysis
Traditional Risk Management Tools		Estimate-based Approach	Expert Judgment-Based Hazard ID	Expert Judgment-Based Criticality Assessment
Frame-by-Frame Technology		Object-based Approach	Object-based Hazard ID	Object-based Criticality Calculation



## The Process Knowledge Database Foundation to create a Digital Process Twin





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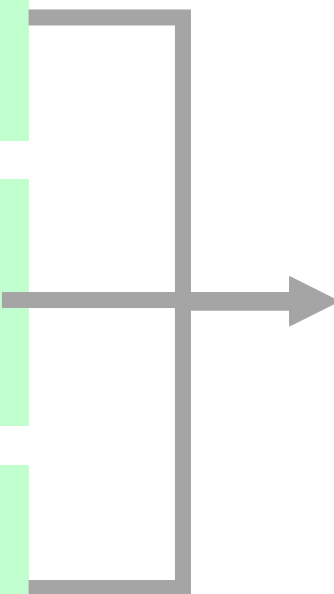
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Scientific papers, Technical Reports and SME Interviews

Regulatory Surveillance and QA Oversight Data

Process Simulation Data and Deviation Reports



## Hazard Library

Comprehensive repository of things that can go wrong in manufacturing



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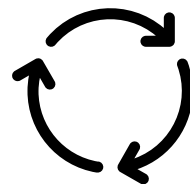
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**FbF First Principle: Certain hazards only occur within the context of specific process frames**



**Process Frame**

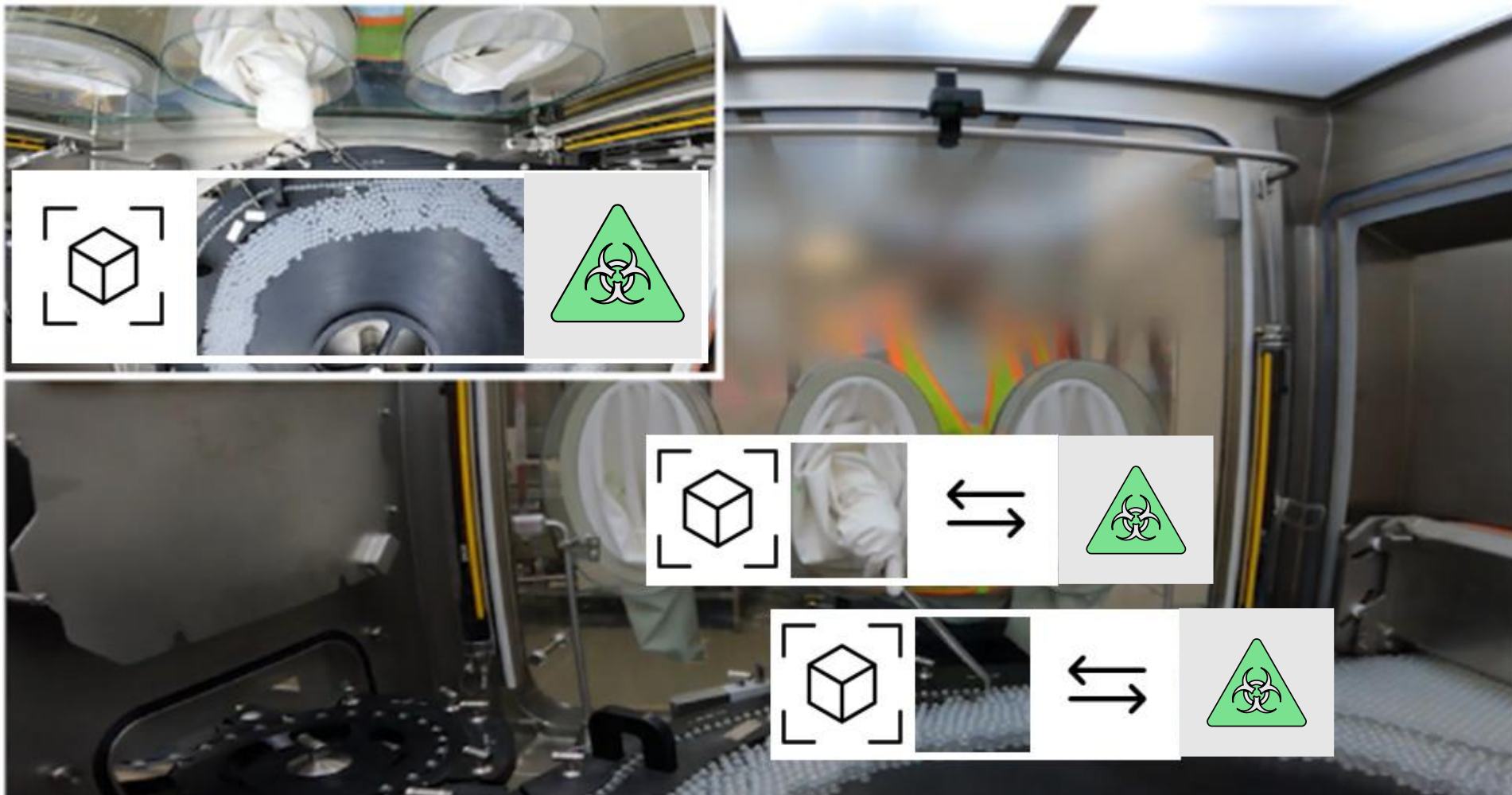


**Hazards**



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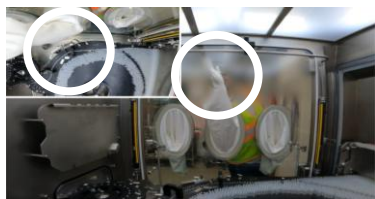
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## Hazard scenario

Insufficient inspection of isolator gloves – front side (4)

Insufficient inspection of isolator gloves – back side (4)

Touching non-sterile surface while inspecting isolator gloves

Tweezer tip touched with isolator glove

Incorrectly grabbing sterile tweezer

Overreaching open vials while grabbing sterile tweezer

Sterile tweezer touches non-sterile surface while transfer

Hold sterile tweezer not tip facing upwards

No visual inspection of sterile tweezer before usage

## Hazard Screening Statistics

Screened Hazard-Scenarios: 450



Assigned Hazard-Scenarios: 9



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Approach	Method		Hazard ID
Traditional Risk Management Tools		Estimate-based Approach	Expert Judgment-Based Hazard ID
<b>Frame-by-Frame Technology</b>		<b>Object-based Approach</b>	<b>Object-based Hazard ID</b>



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## Formula for Weighted Hazard Criticality (WHC)

$$WHC = WH_{sev} * WH_{lik}$$

$$WHC = \underbrace{(H_{sev} \cdot RM_{sev})}_{WH_{sev}} \cdot \underbrace{(H_{lik} \cdot RM_{lik})}_{WH_{lik}}$$

Severity

Likelihood



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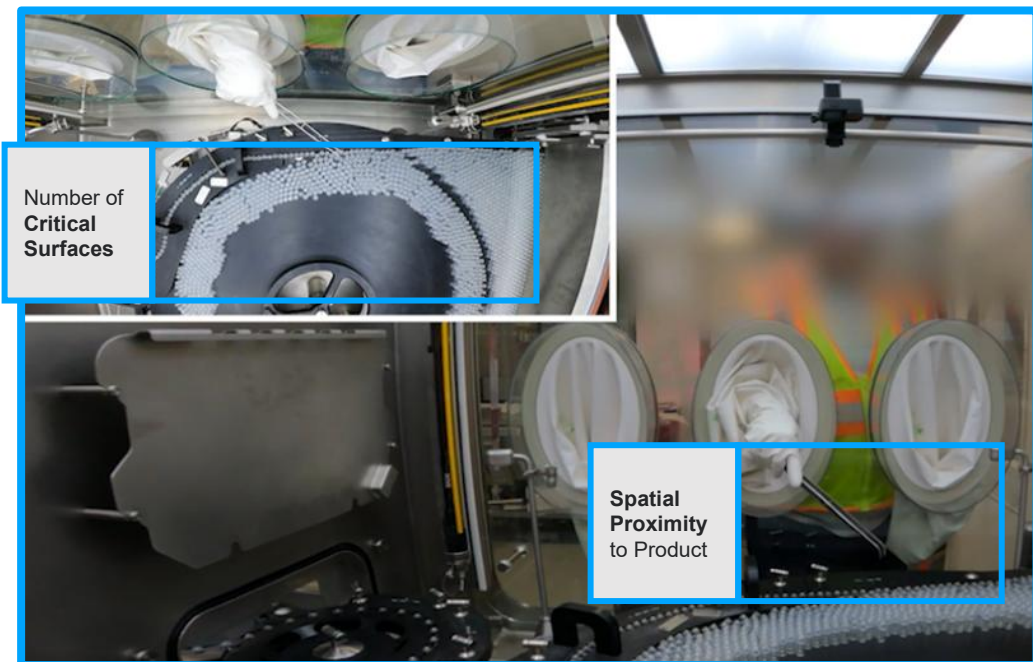
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## Formula for Weighted Hazard Criticality (WHC)

$$WHC = WH_{sev} * WH_{lik}$$

$$WHC = \underbrace{WH_{sev}}_{(H_{sev} \cdot RM_{sev})} \cdot \underbrace{WH_{lik}}_{(H_{lik} \cdot RM_{lik})}$$



## Formula for unweighted hazard severity

$$H_{sev} = s1 * \text{Number of critical surfaces} + s2 * \text{Product sterilization status} + s3 * \text{Product condition} + s4 * \text{Spatial proximity to product}$$

Where:  $s1 = s2 = 0.3; s3 = s4 = 0.2; s1 + s2 + s3 + s4 = 1$

## Formula for Hazard Severity risk moderator

$$RM_{sev} = 1 + \text{Batch recoverability} + \text{Decontamination status} + \text{Barrier system} + \text{Gowning} + \text{Interaction with critical surface}$$

$$H_{sev-base} = 1 - RM_{sev-min} = 0.5$$



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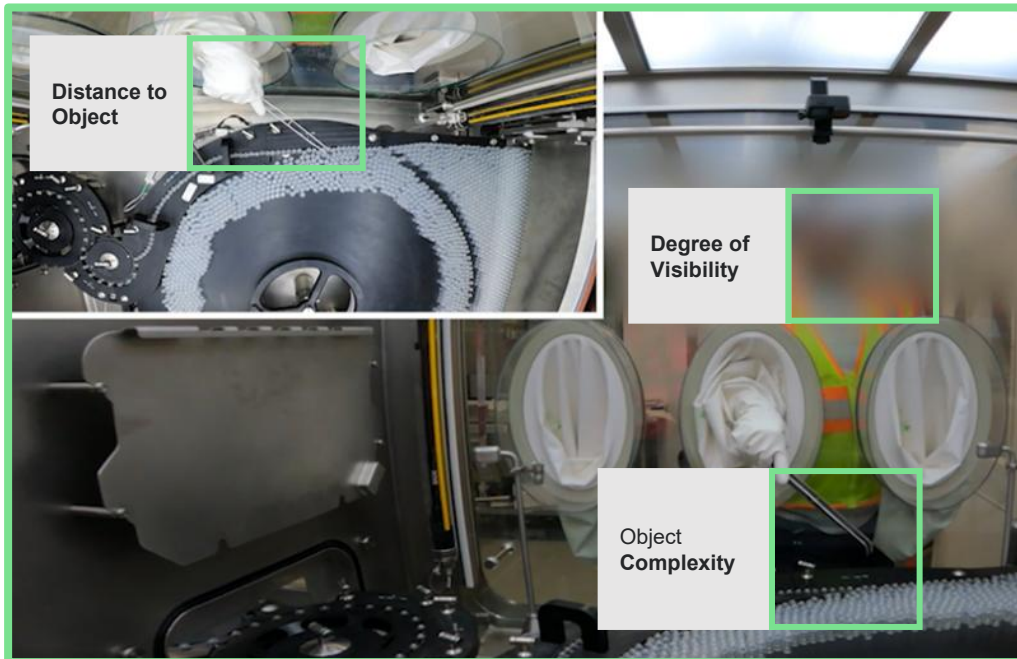
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## Formula for Weighted Hazard Criticality (WHC)

$$WHC = WH_{sev} * WH_{lik}$$

$$WHC = \underbrace{(H_{sev} \cdot RM_{sev})}_{WH_{sev}} \cdot \underbrace{(H_{lik} \cdot RM_{lik})}_{WH_{lik}}$$



## Formula for unweighted hazard likelihood

$$H_{lik} = l1 * \text{Number of active objects} + l2 * \text{Ergonomic freedom} + l3 * \text{Complexity}$$

Where  $l1 = l2 = l3 = \frac{1}{3}$ ;  $l1 + l2 + l3 = 1$

$$\text{Ergonomic freedom} = \alpha * \text{Degree of visibility} + \beta * \text{Distance to object} + \gamma * \text{Degree of tactility}$$

Where  $\alpha = 0.5$ ;  $\beta = \gamma = 0.25$ ;  $\alpha + \beta + \gamma = 1$

$$\text{Complexity} = \text{AVG}(\text{handling} + \text{weight} + \text{size})$$

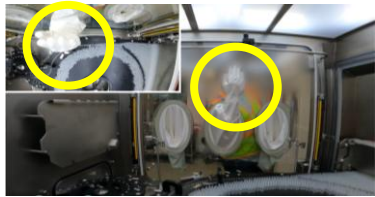
## Formula for hazard likelihood risk moderator

$$RM_{lik} = 1 + \text{Allowed movement speed} + \text{Execution pace} + \text{Frame progress tracker}$$



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Hazard scenario	Criticality	WHC*
Insufficient inspection of isolator gloves – front side (4)	Minor	12.6
Insufficient inspection of isolator gloves – back side (4)	Minor	13.9
Touching non-sterile surface while inspecting isolator gloves	Minor	14.1
Tweezer tip touched with isolator glove	Major	23.0
Incorrectly grabbing sterile tweezer	Major	19.0
Overreaching open vials while grabbing sterile tweezer	Major	17.2
Sterile tweezer touches non-sterile surface while transfer	Major	17.2
Hold sterile tweezer not tip facing upwards	Major	14.8
No visual inspection of sterile tweezer before usage	Major	15.2

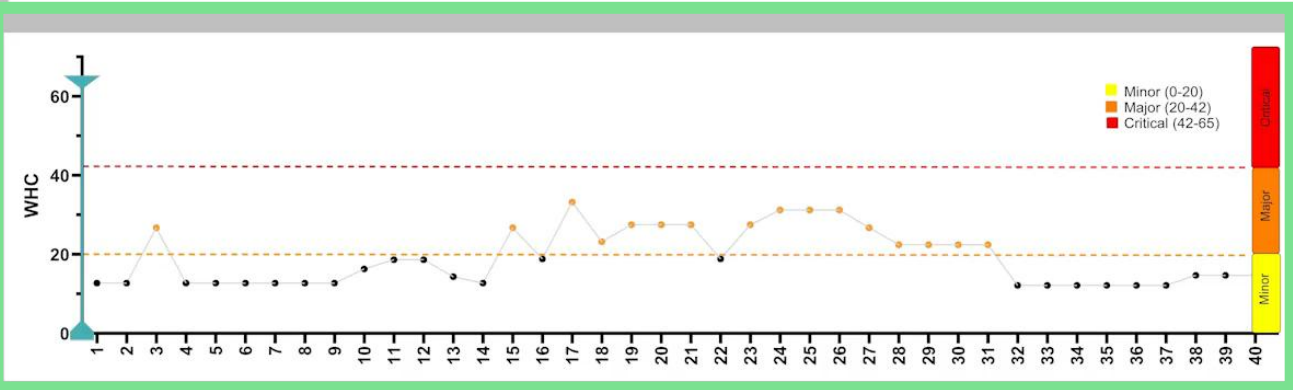


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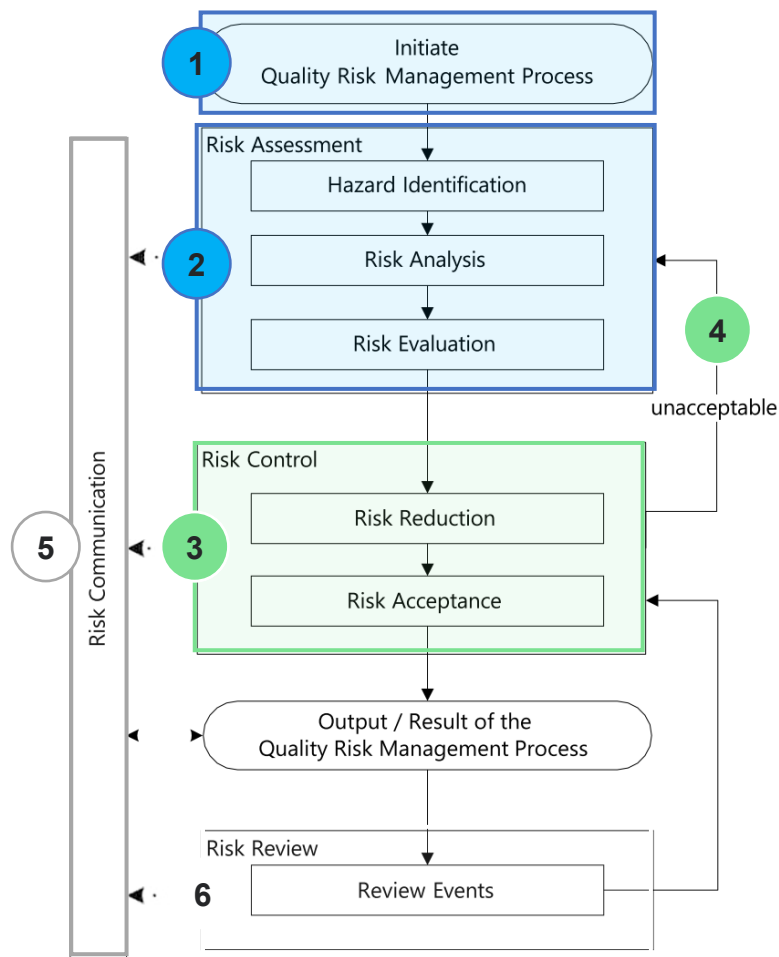
Remove vial jam





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- (1) Process Mapping
- (2) Risk Assessment
- (3) **Process Design**
- (4) Risk Control
- (5) Risk Communication

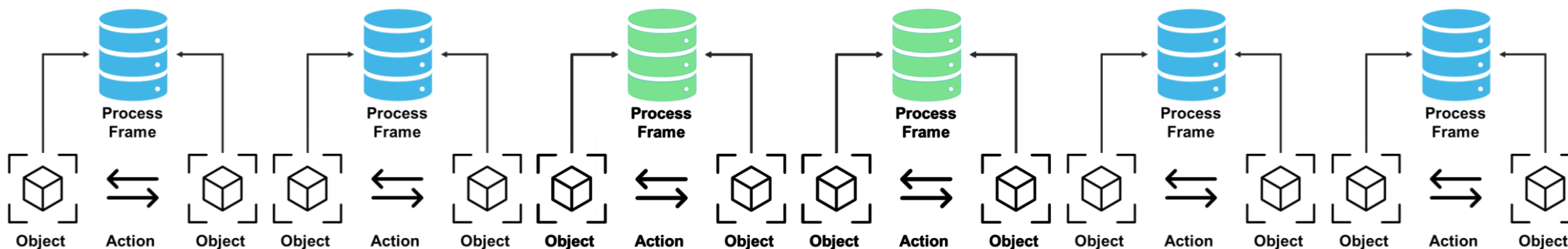


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## Establishing reliable reference data **Frame-In-Frame-Out**

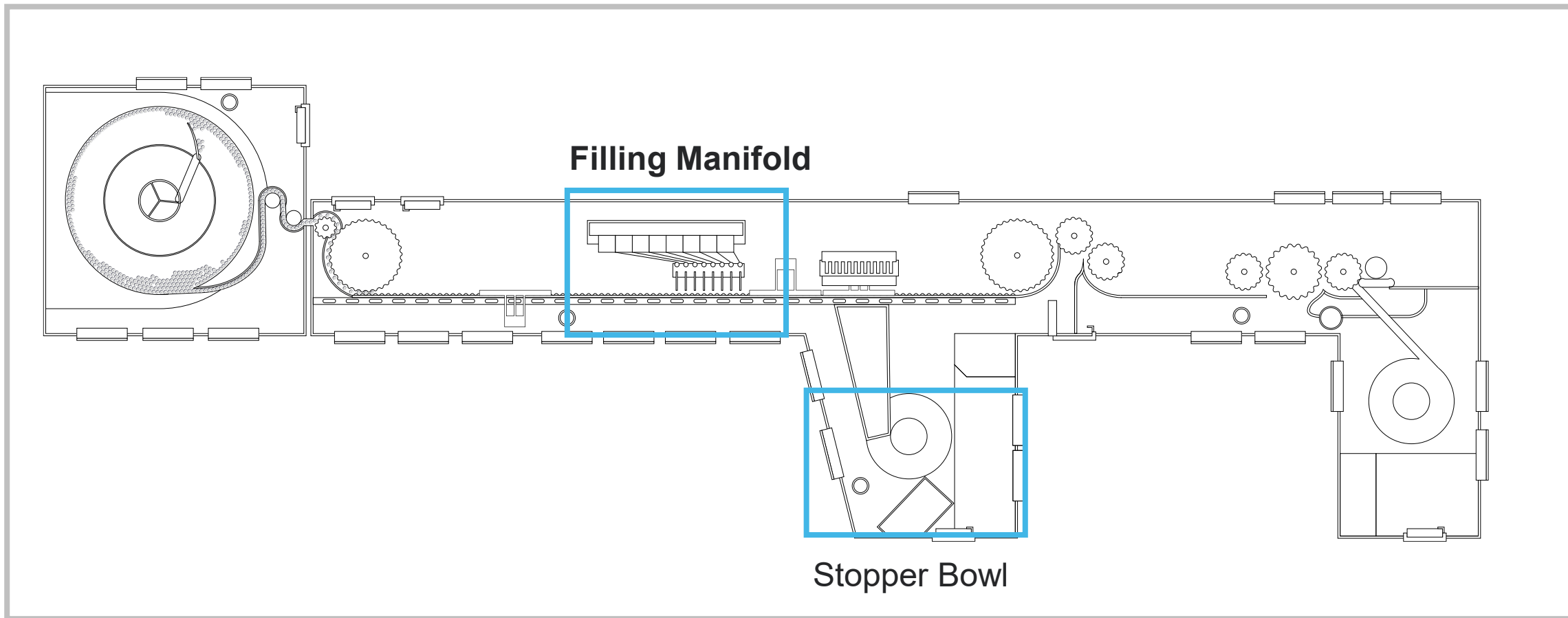


Every manufacturing process can be defined  
**as a sequence of Process Frames.**



# Frame-by-Frame Assurance & Quality Risk Filling Manifold Installation

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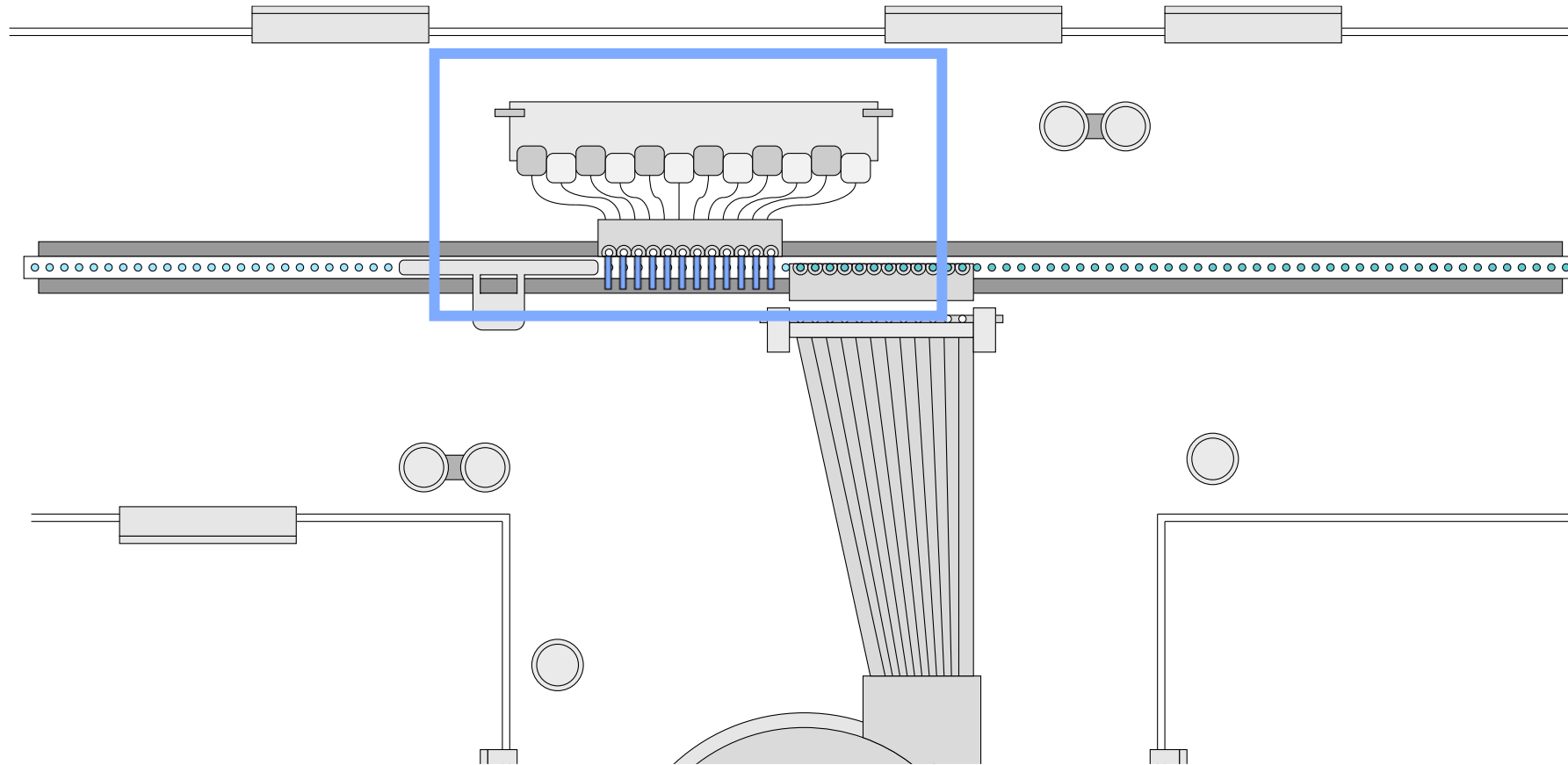




# Frame-by-Frame Assurance & Quality Risk Management Conference

- Filling Manifold Installation

October 8<sup>th</sup> & 9<sup>th</sup>

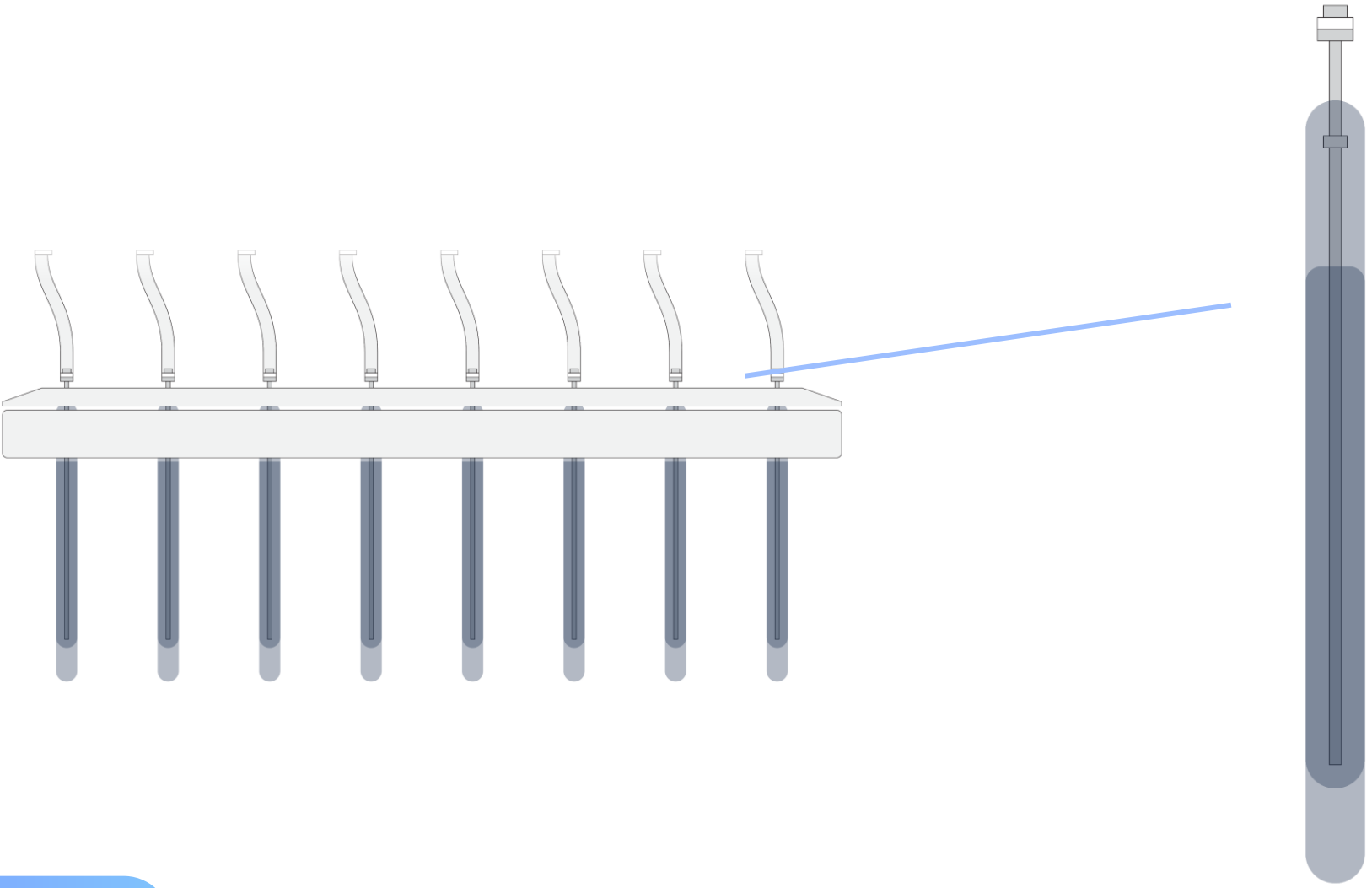




# Case Study: Sterility Assurance & Quality Risk Management Conference

## Process Modelling for „Uncovering Filling Needs“

October 8<sup>th</sup> & 9<sup>th</sup>





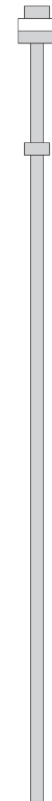
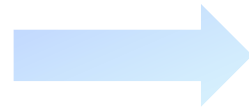
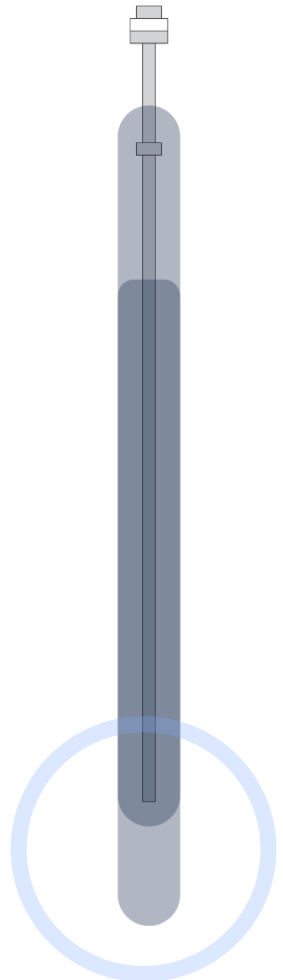
Case Study

# Sterility Assurance & Quality Risk Management Conference

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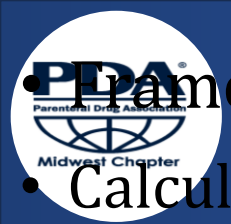
• Process Modelling for „Uncovering Filling Needles“



Uncovered needle



Needle cover

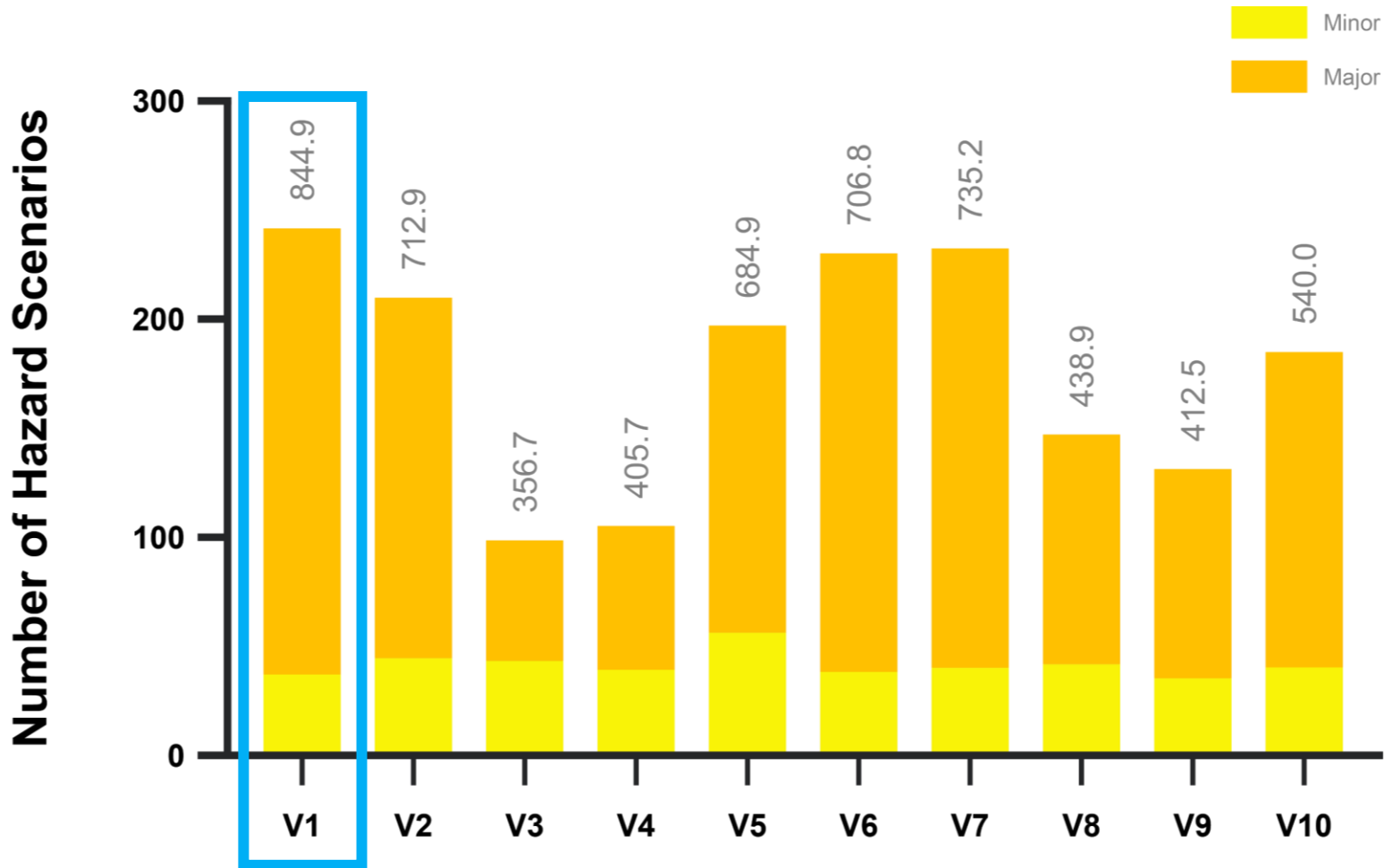


# Frame-by-Frame Assumptions & Quality Risk Management Conference

October 8th & 9th



- Calculated risk of ten primary ways to uncover the needles

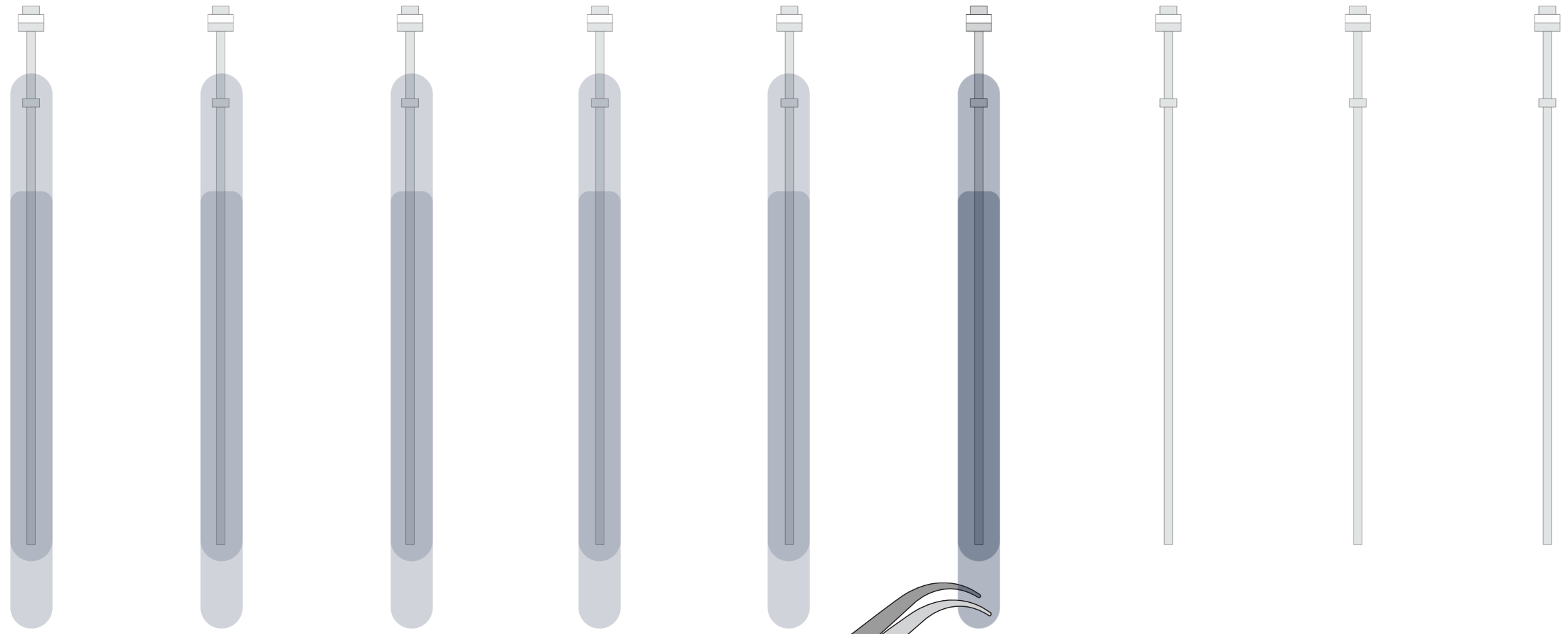




# Case Study: Sterility Assurance & Quality Risk Management Conference

## „Uncovering Filling Needles“

October 8<sup>th</sup> & 9<sup>th</sup>



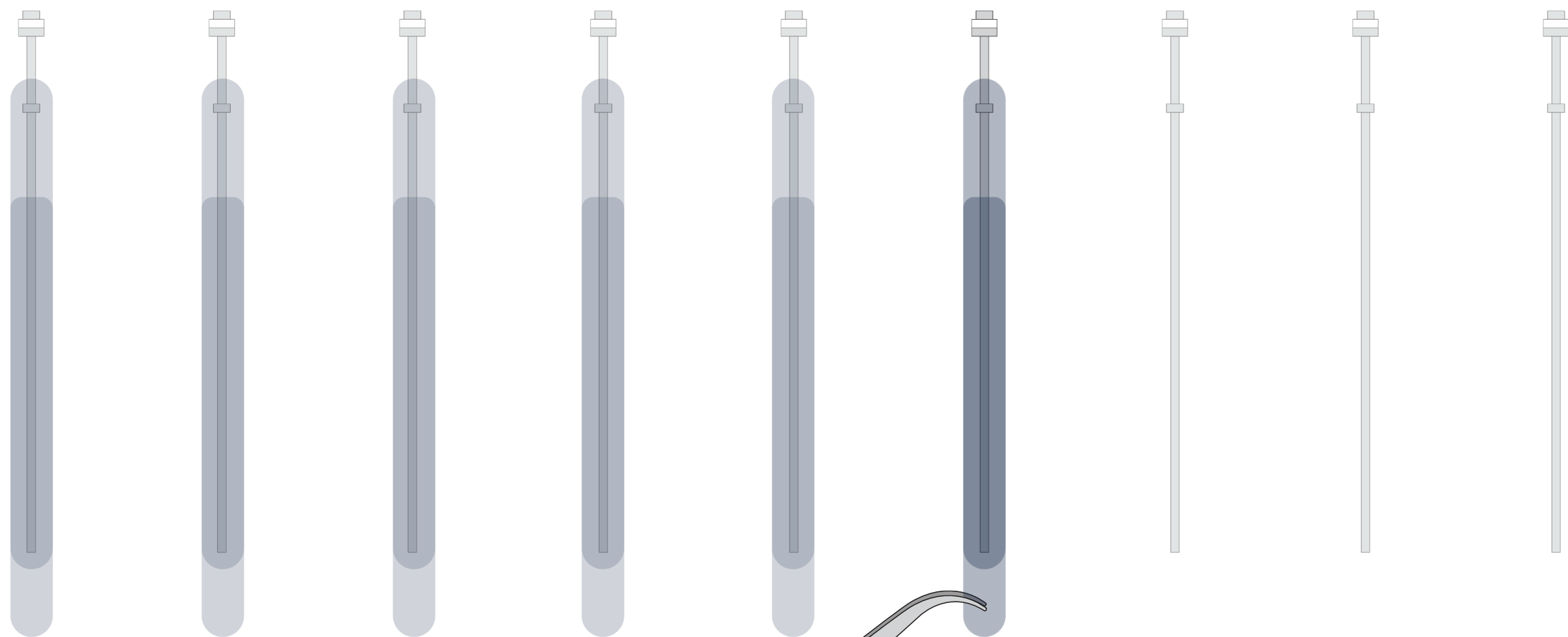
Process Design



# Case Study: Sterility Assurance & Quality Risk Management Conference

## „Uncovering Filling Needs“

October 8<sup>th</sup> & 9<sup>th</sup>



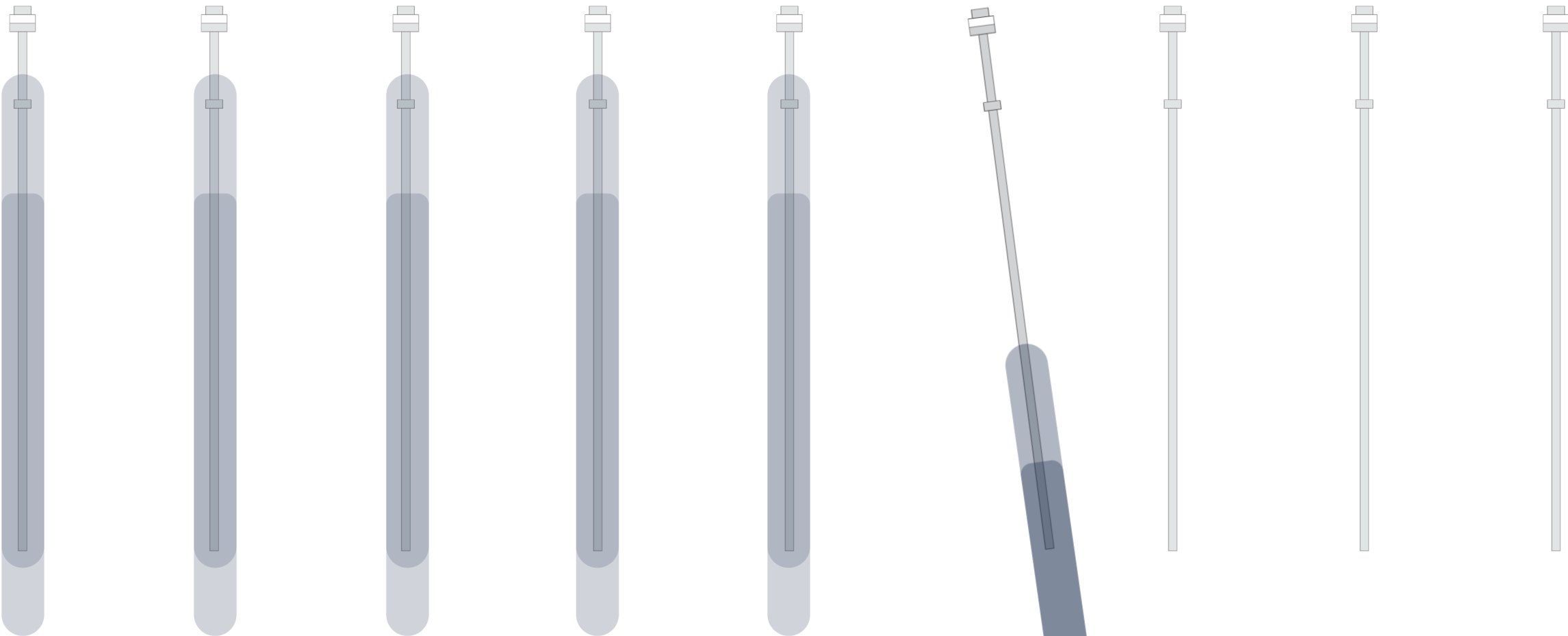
Process Design



# Case Study: Sterility Assurance & Quality Risk Management Conference

## „Uncovering Filling Needs“

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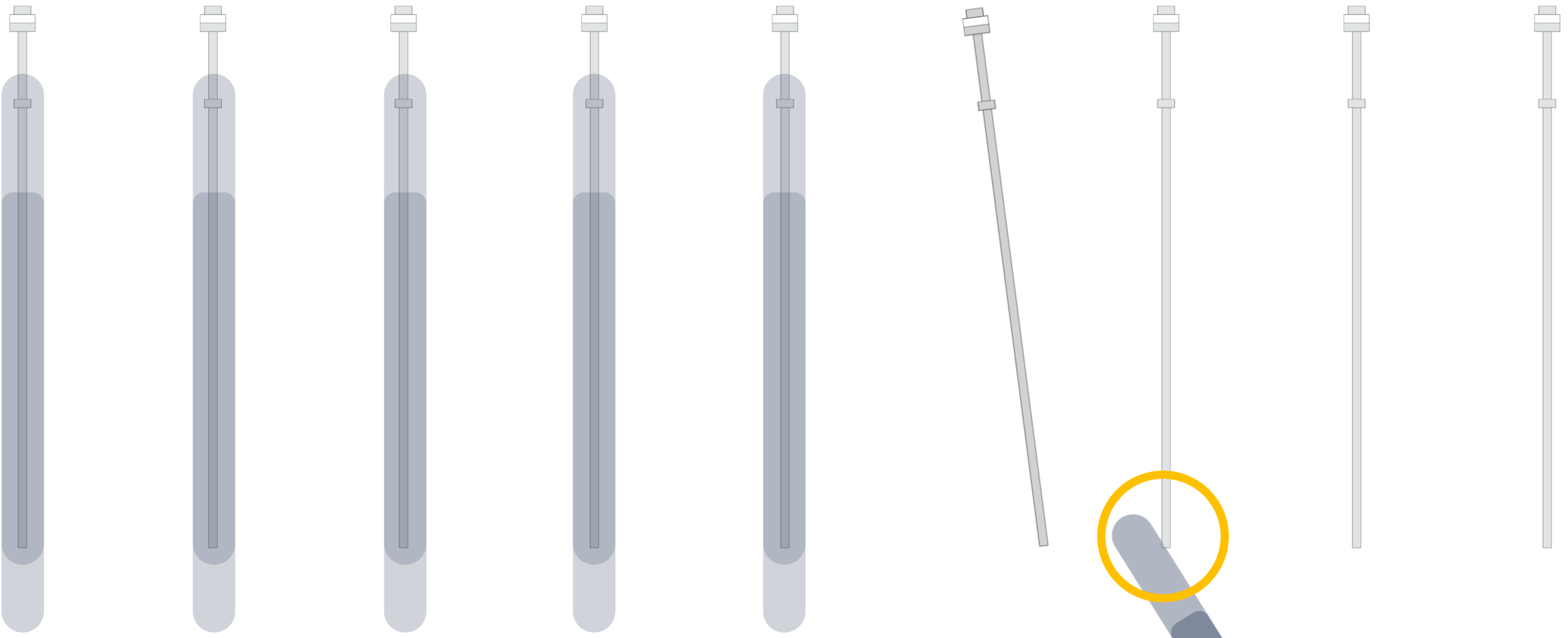




# Case Study: Sterility Assurance & Quality Risk Management Conference

## „Uncovering Filling Needs“

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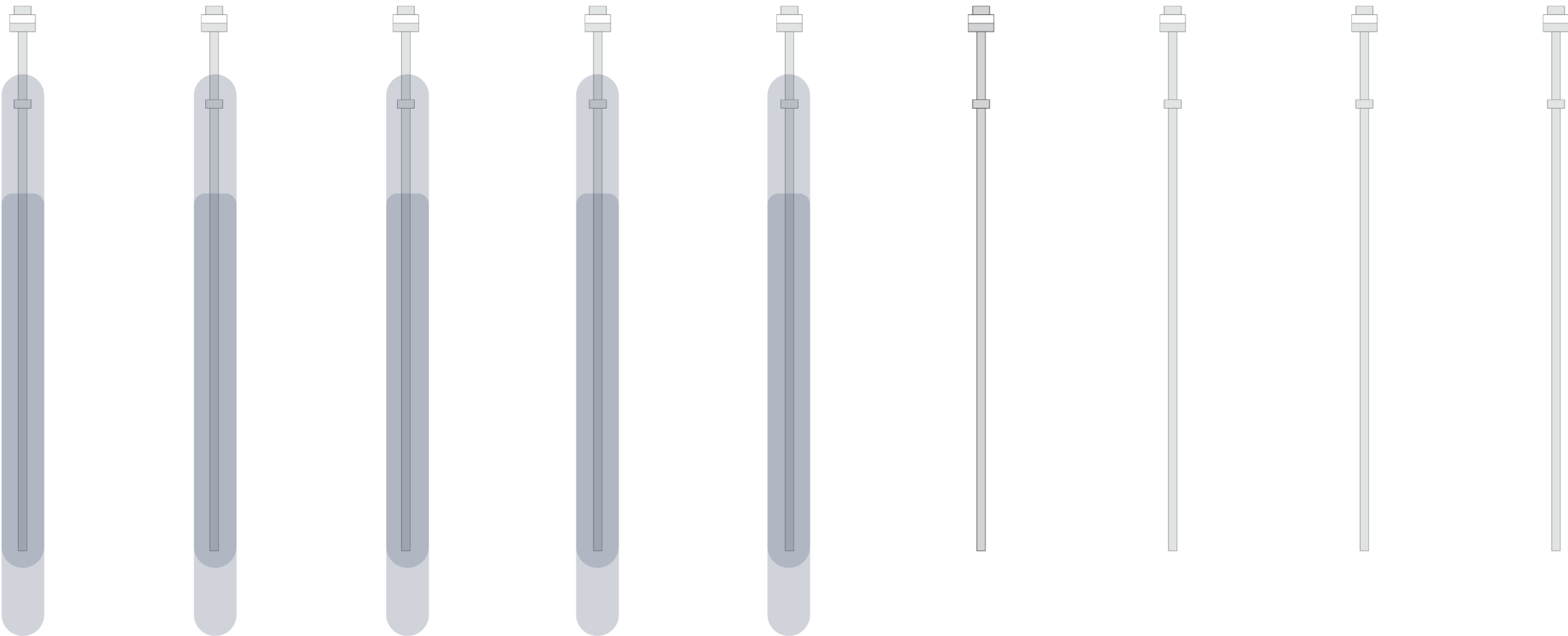




# Case Study: Sterility Assurance & Quality Risk Management Conference

## „Uncovering Filling Needs“

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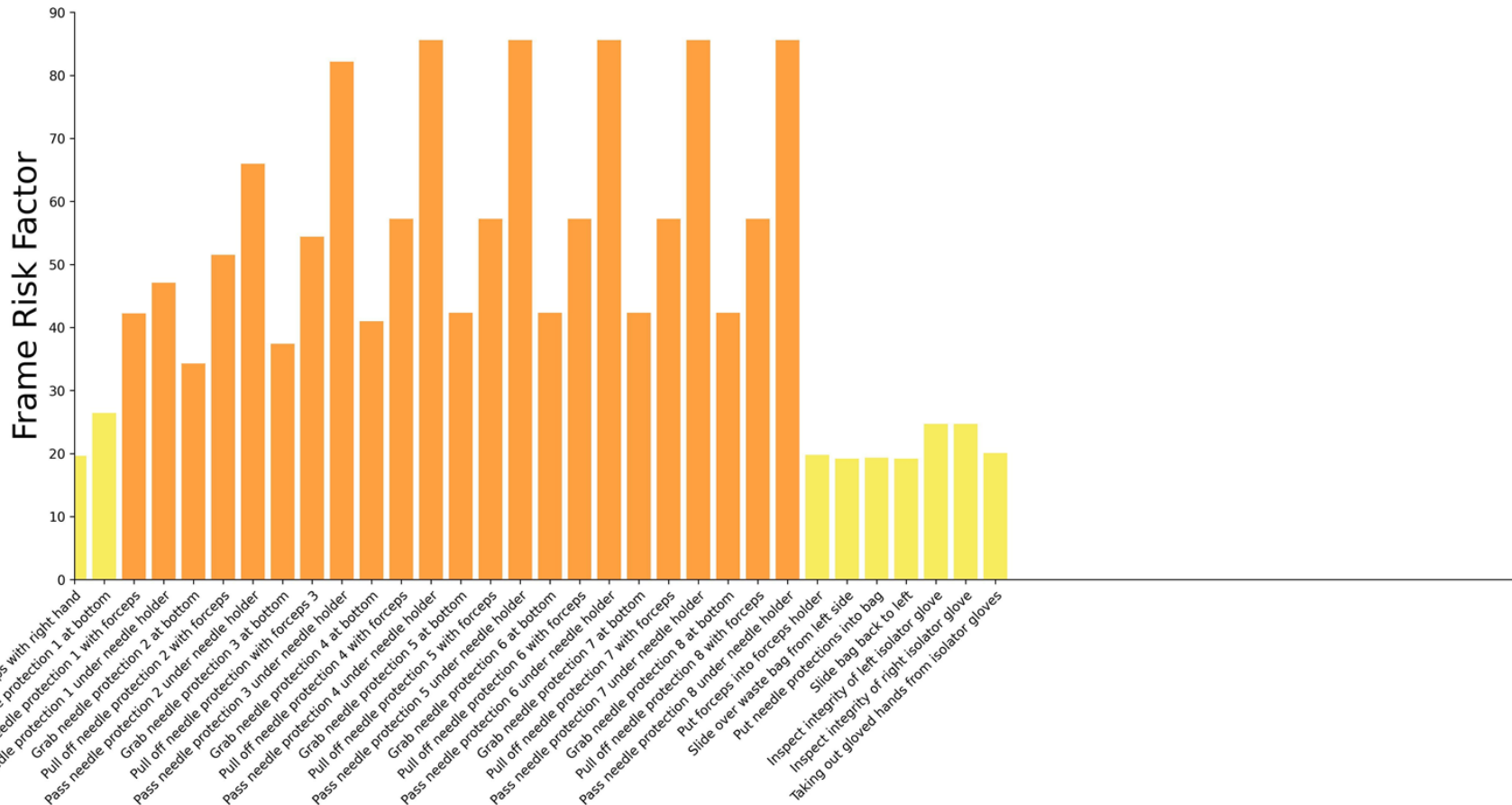


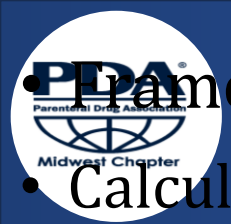


# Frame-by-Frame Assumptions & Quality Risk Management Conference

- Risk in Process Variant 1

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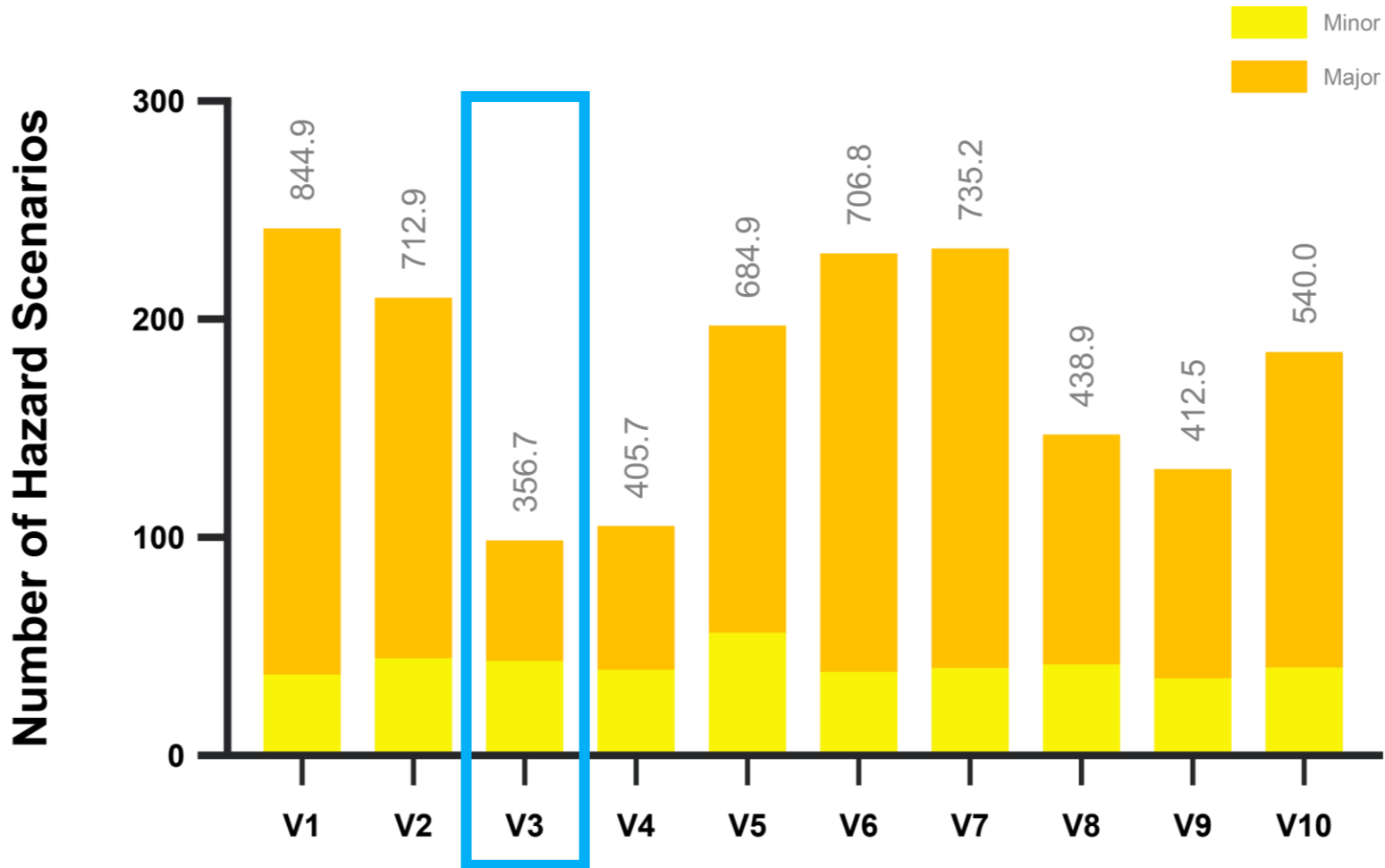


# Frame-by-Frame Assumptions & Quality Risk Management Conference

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- Calculated risk of ten primary ways to uncover the needles





# Sterility Assurance & Quality Risk Management Conference

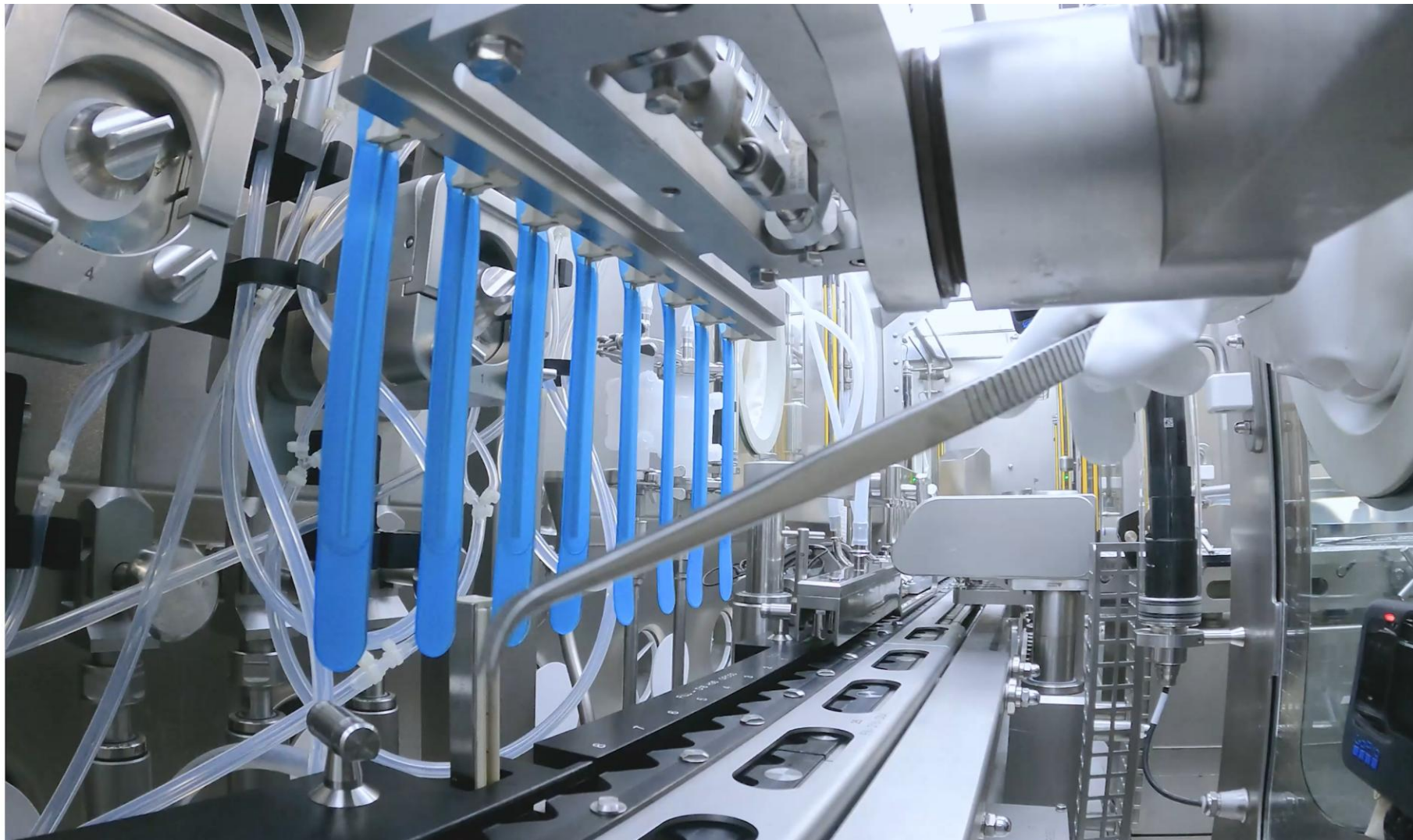
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## Task 3 (3/6)

### Remove needle protection

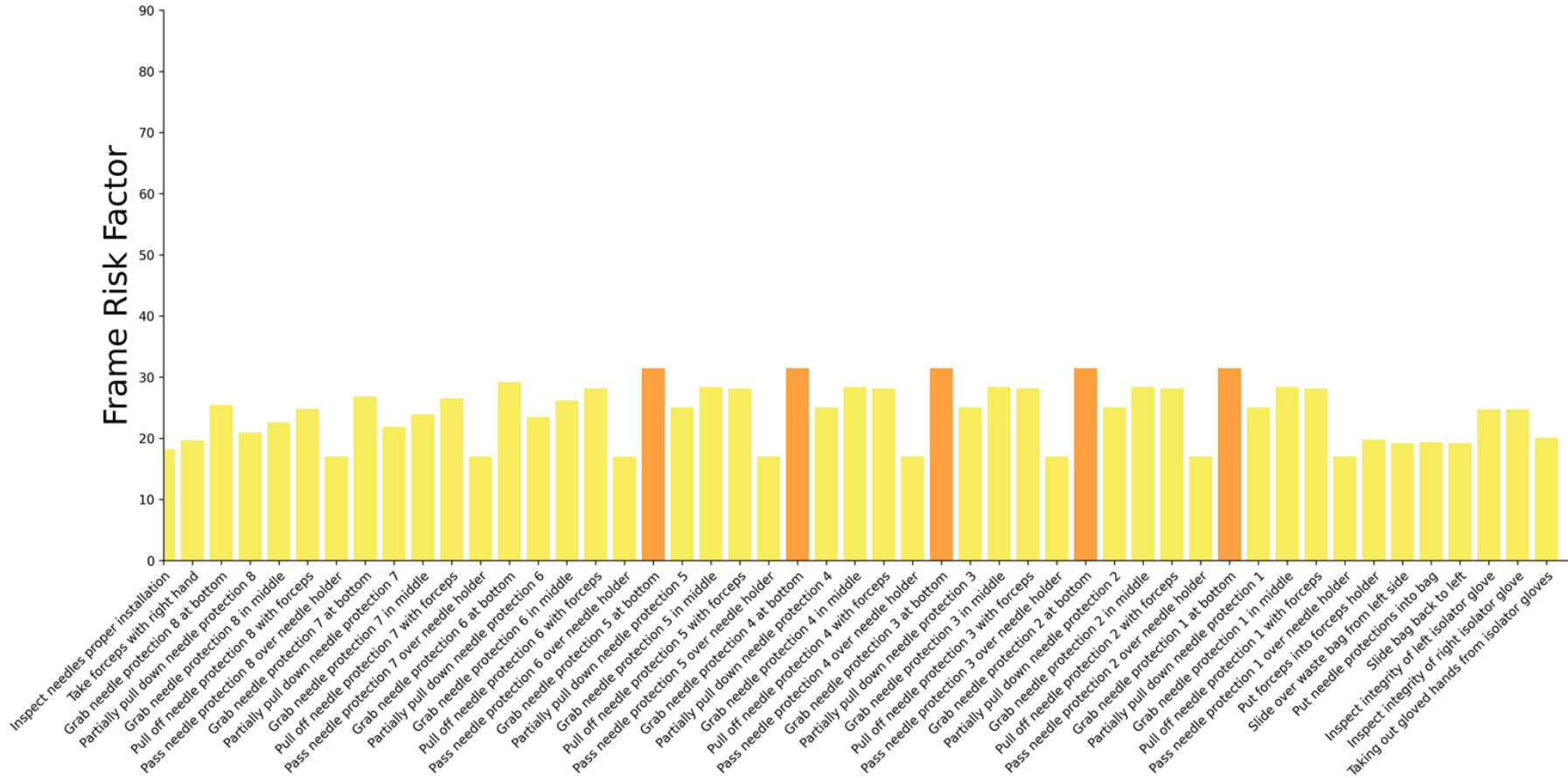
- Grasp bottom of needle protection with forceps (needle 8)





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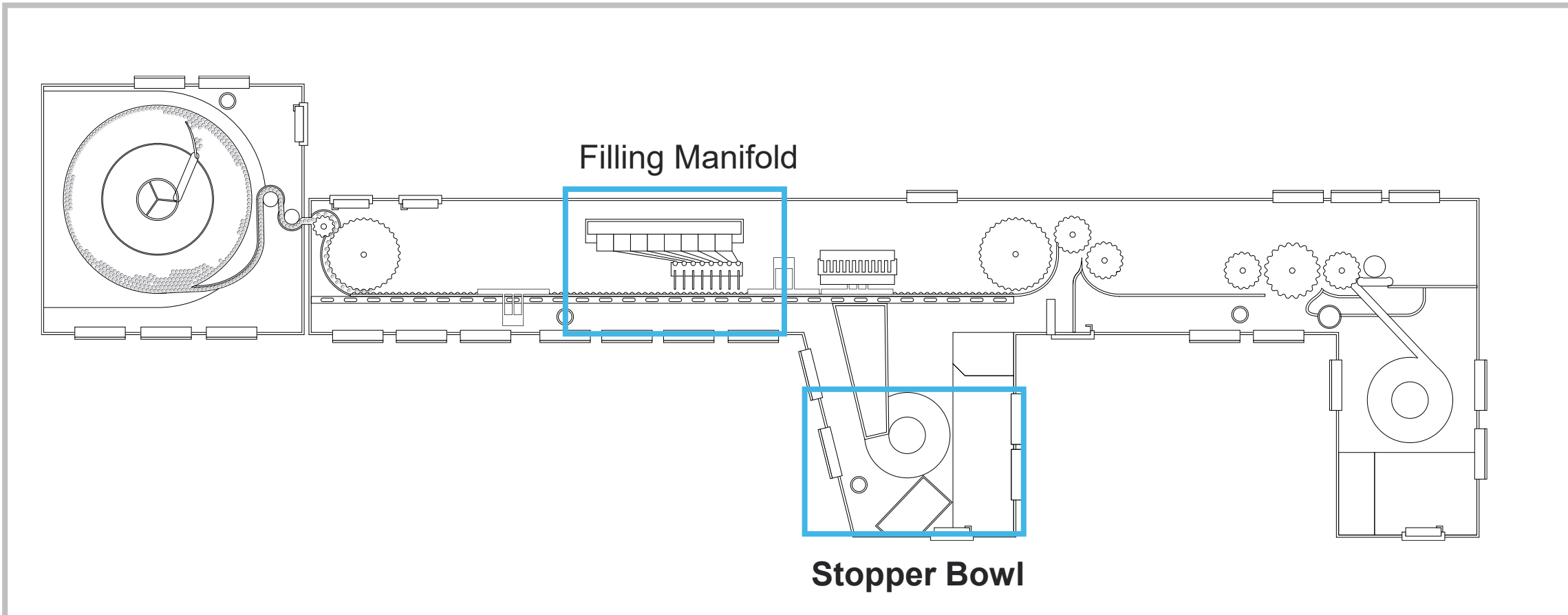
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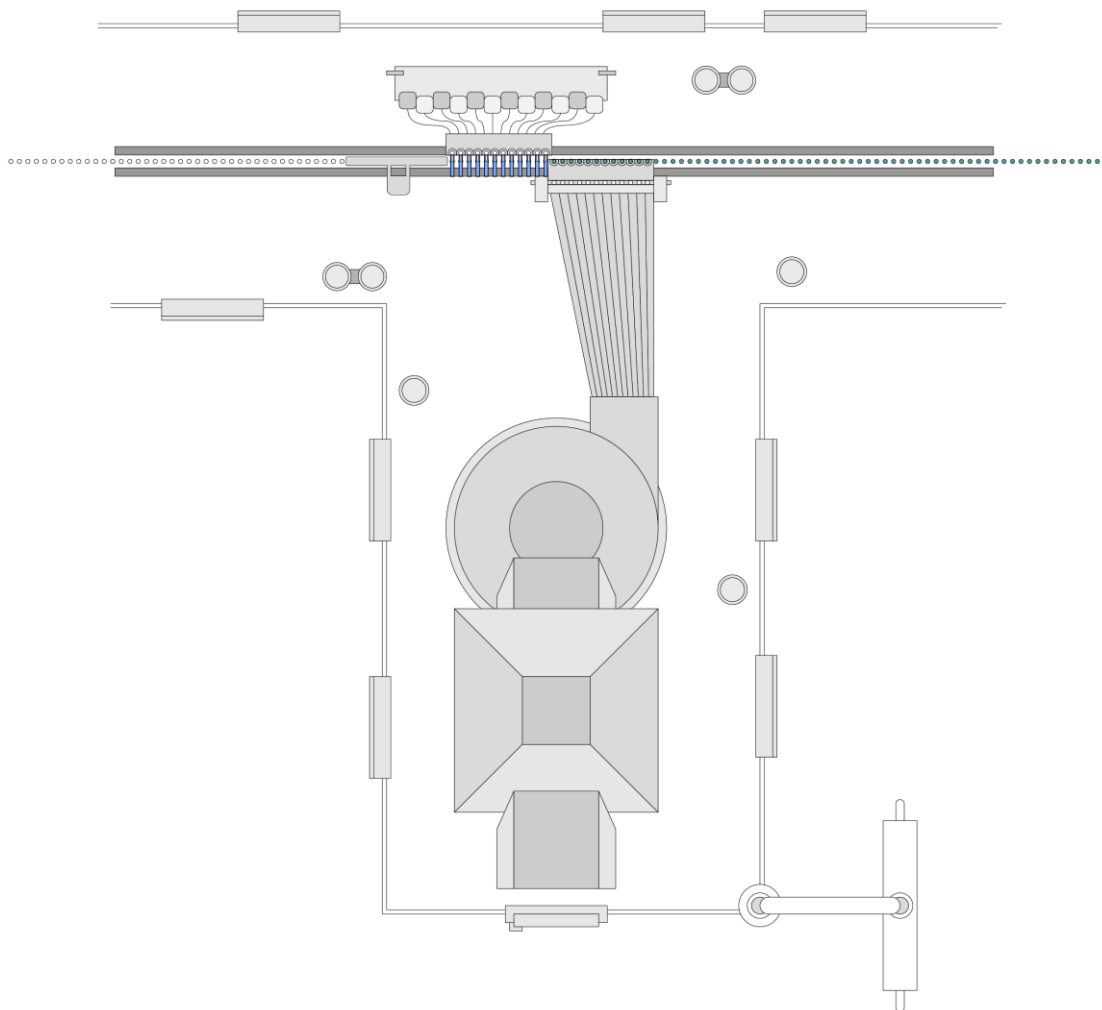
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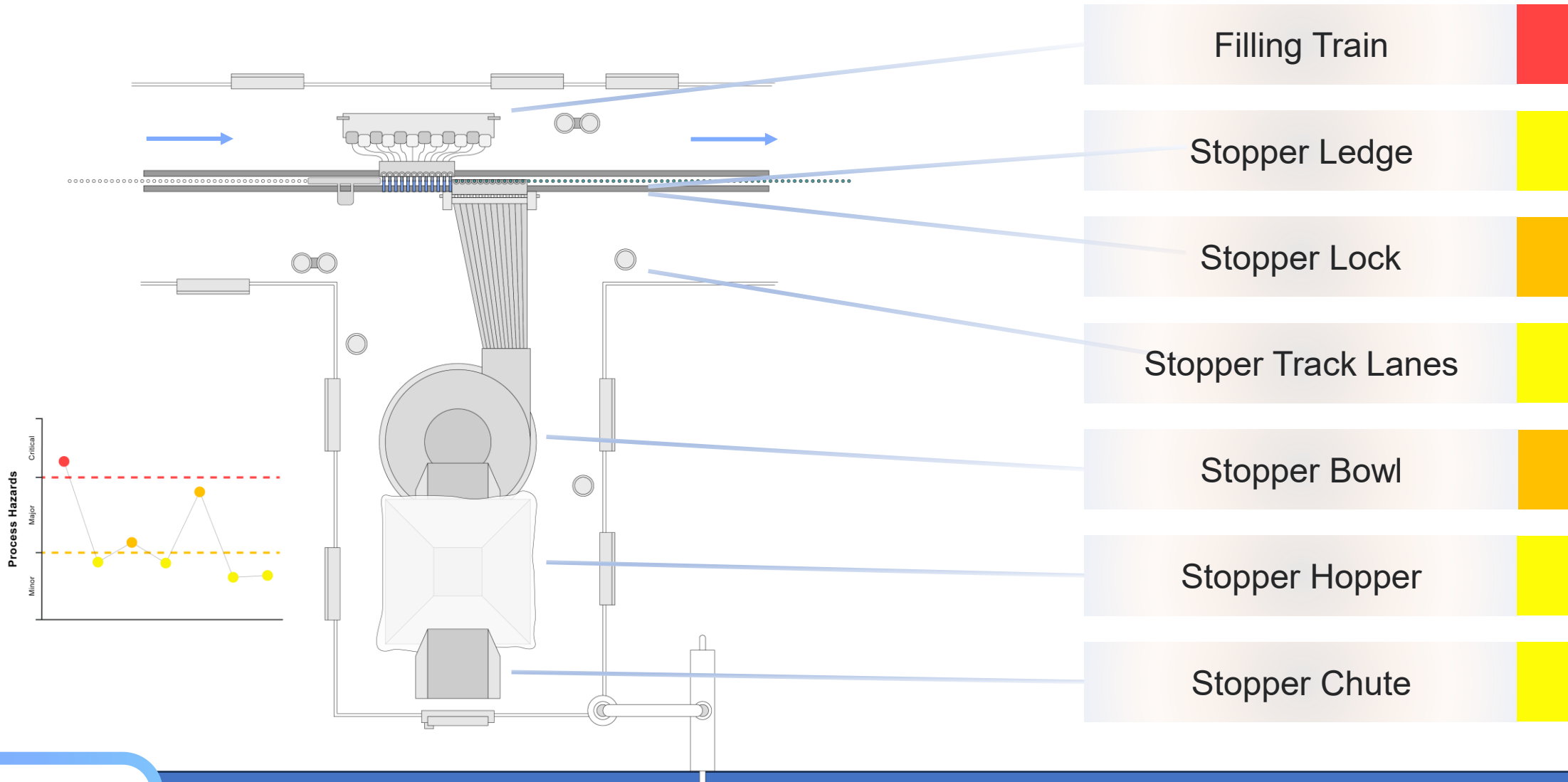
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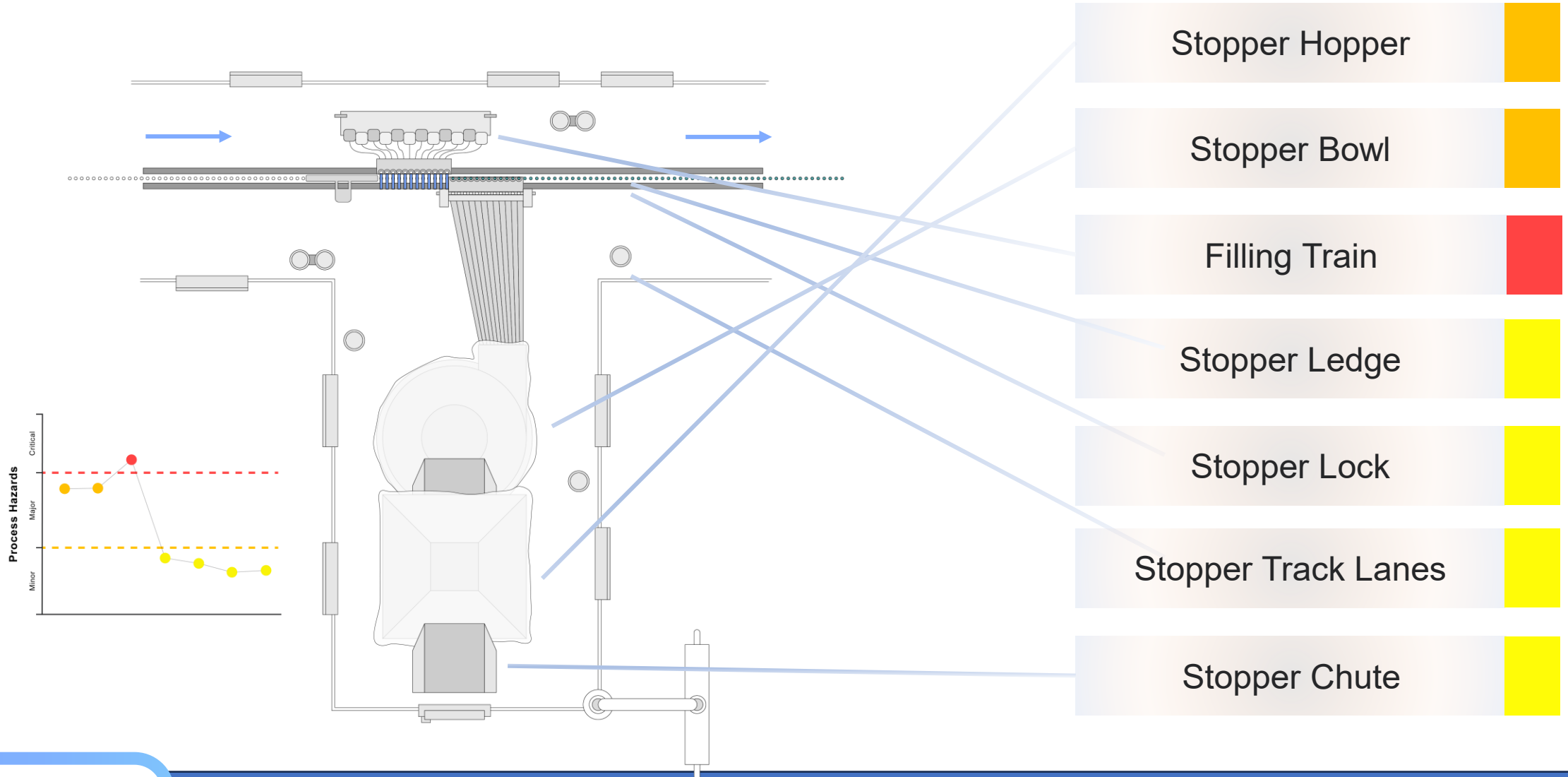
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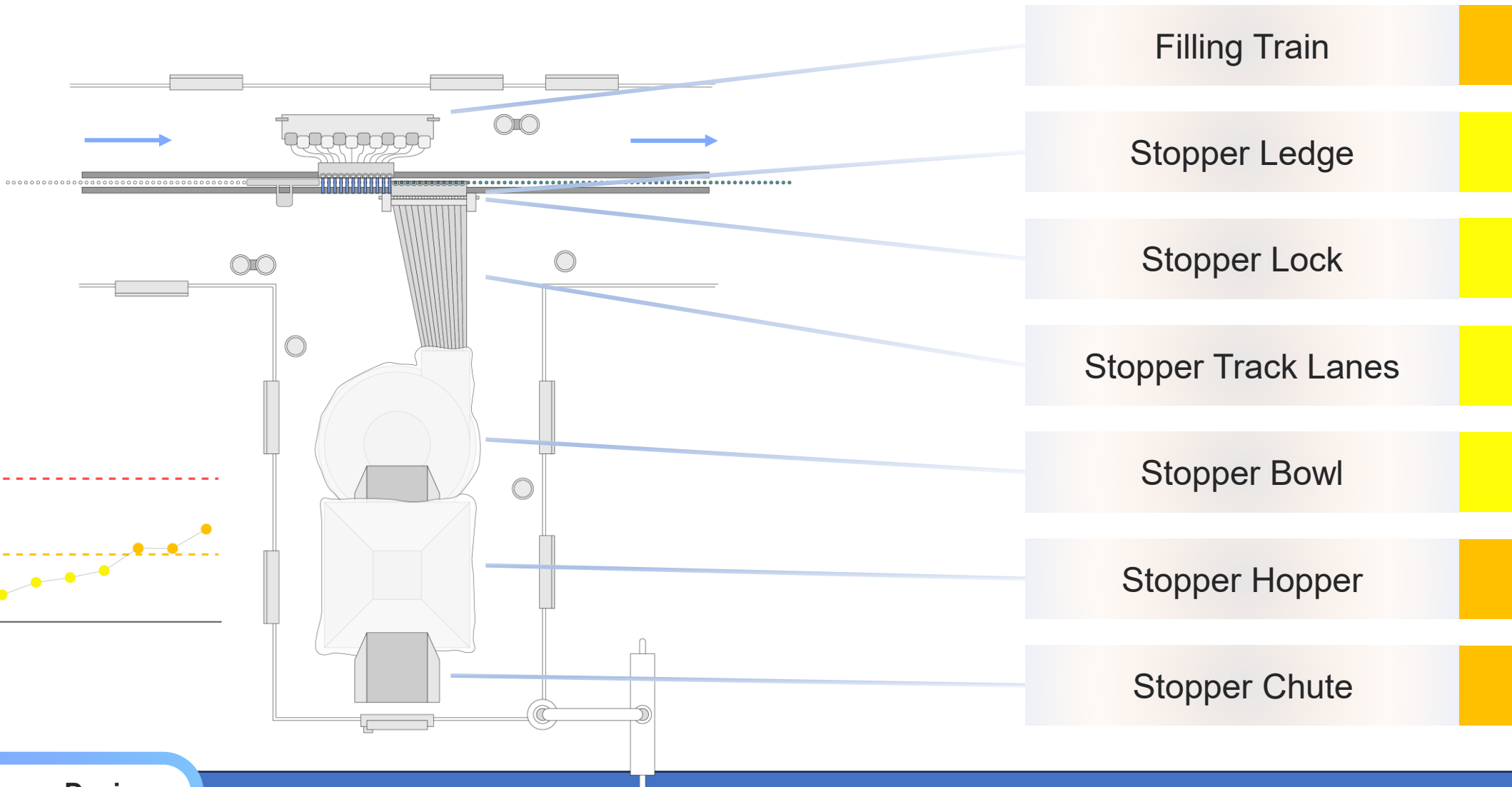
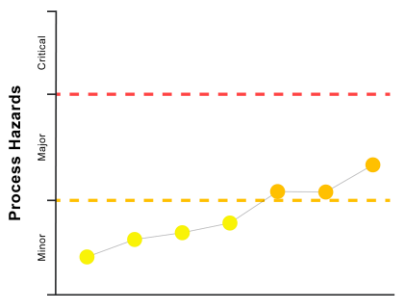
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# Sterility Assurance & Quality Risk Management Conference

October 8<sup>th</sup> & 9<sup>th</sup>

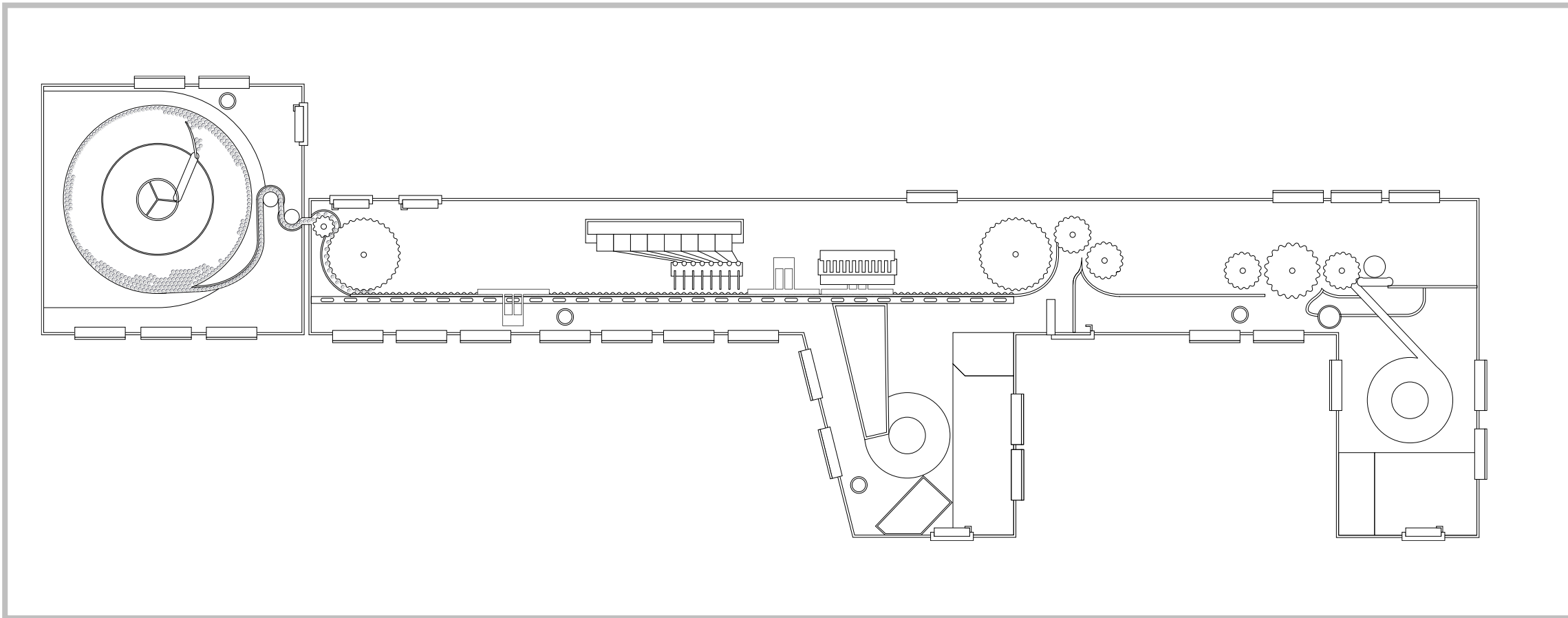






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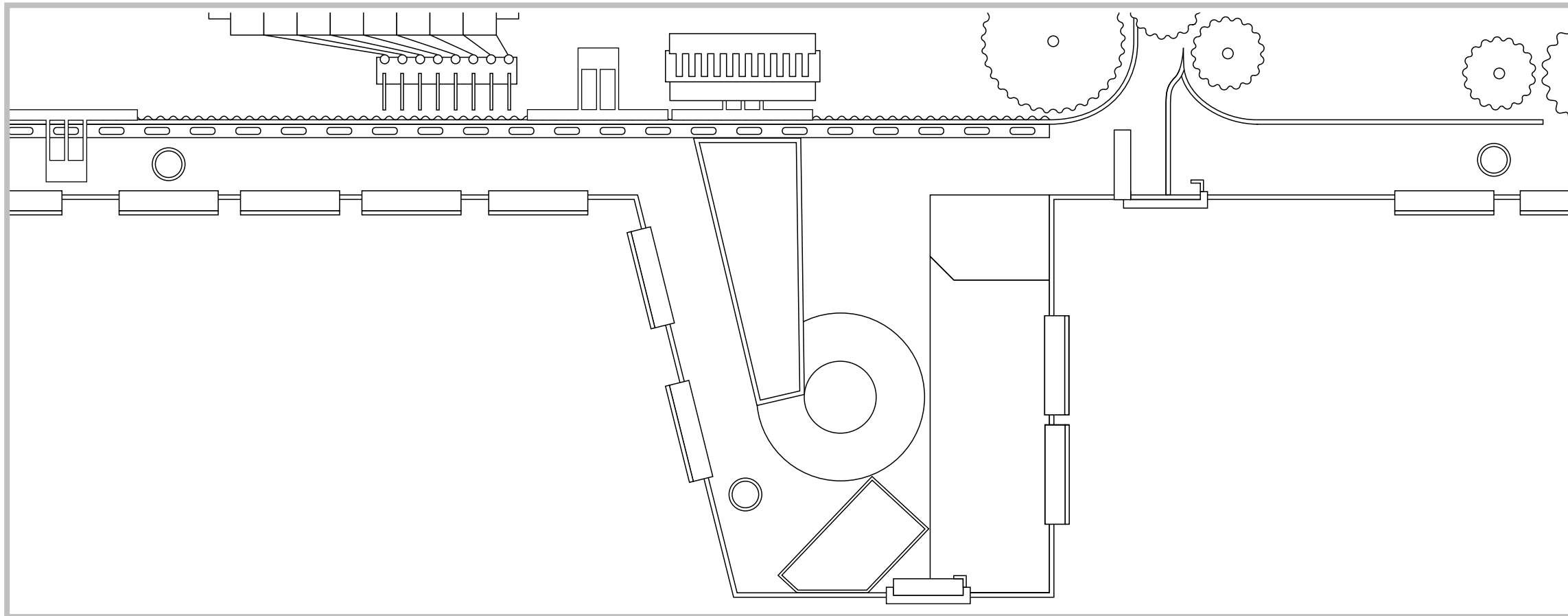
October 8<sup>th</sup> & 9<sup>th</sup>





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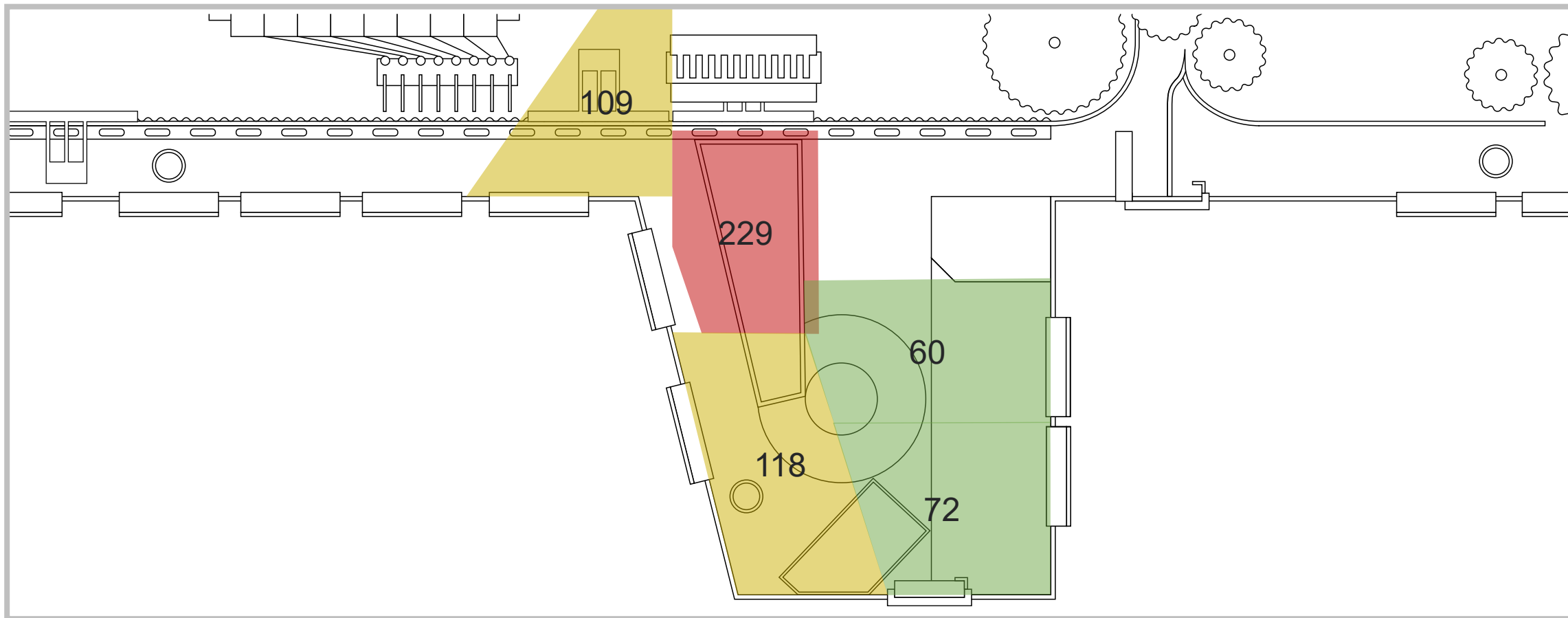
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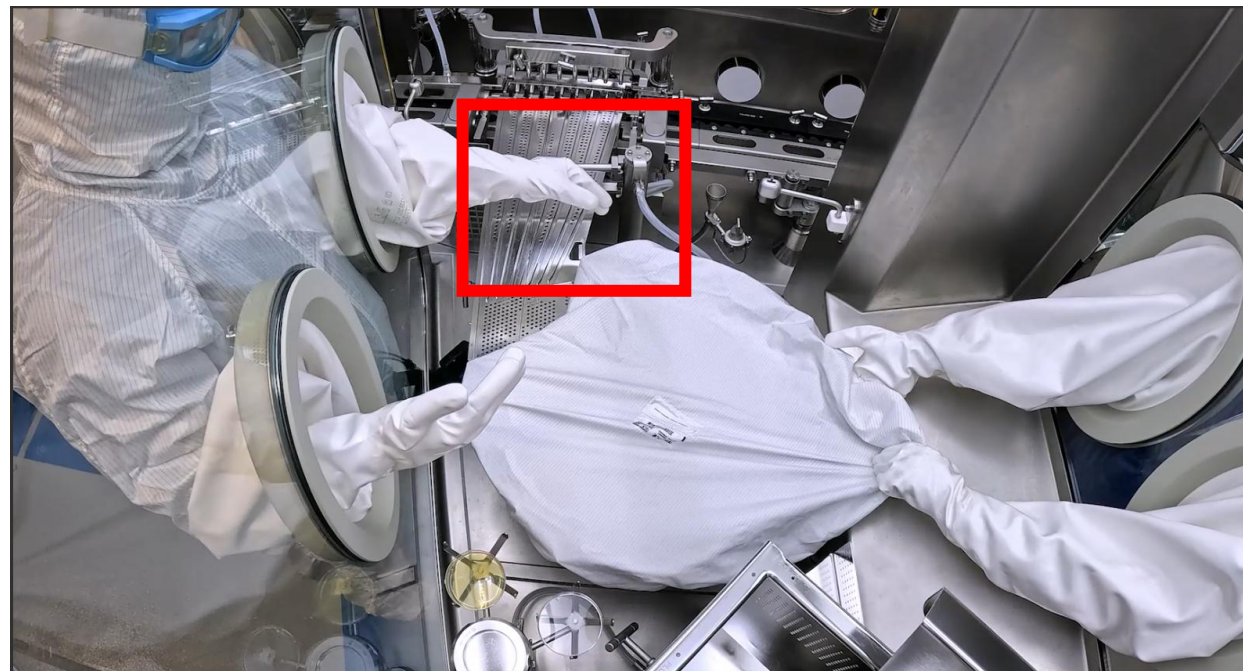
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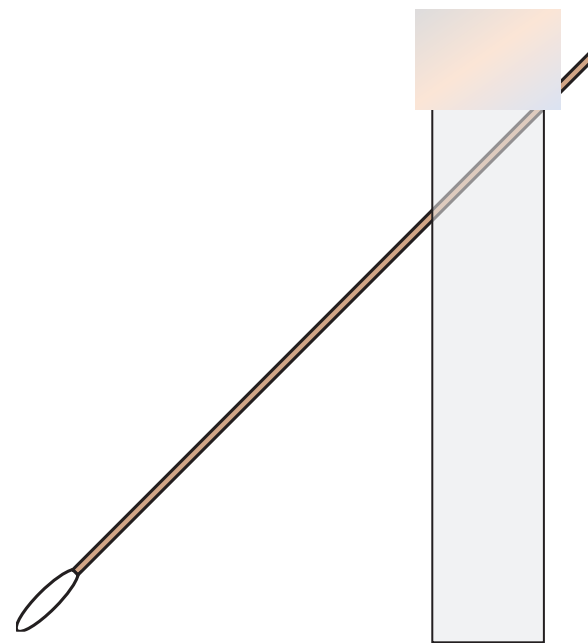
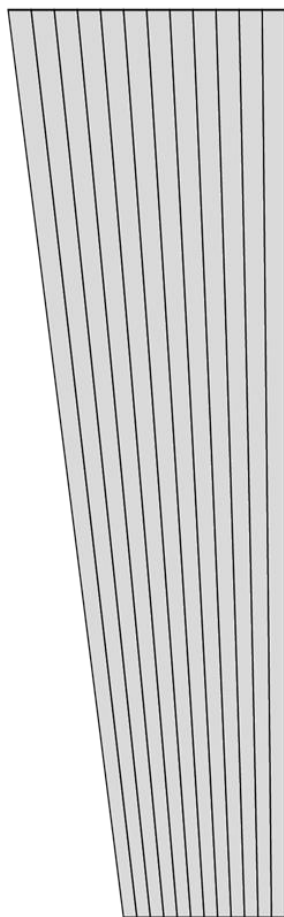


Hazard Identification	Risk Analysis	Risk Assessment		Risk prevention							Risk detectability				Final decision
		Hazard Category	Hazard Specification	CQA affected	CRF	Pre-installation sterilization	Post-installation sterilization	Equipment Design	Equipment Qualification	Instruction & oversight	Personnel Qualification	Prevention Measures	Sterility assurance tests post-VHP/pre-filling	In-process Sterility assurance tests	
Contaminated components	Contaminated primary bag stopper ledge	Sterility - Purity	25,18	Autoclaving	None	Double-bagging of components	Check-in visual inspection	SOP-instructed	Aseptic technique qualification	6	None	None	None	1	4,20
Contaminated components	Contaminated stopper ledge	Sterility - Purity	104,85	Autoclaving	VHP	Ergonomic layout to reduce unintended touches	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	7	None	None	None	1	14,98
Contaminated components	Contaminated primary bag stopper transfer ledge	Sterility - Purity	25,30	Autoclaving	None	Double-bagging of components	Check-in visual inspection	SOP-instructed	Aseptic technique qualification	6	None	None	None	1	4,22
Contaminated components	Contaminated stopper transfer ledge	Sterility - Purity	95,12	Autoclaving	VHP	None	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	6	None	None	None	1	15,85
Contaminated components	Contaminated primary bag stopper lock	Sterility - Purity	13,12	Autoclaving	None	Double-bagging of components	Check-in visual inspection	SOP-instructed	Aseptic technique qualification	6	None	None	None	1	2,19
Contaminated components	Contaminated stopper lock	Sterility - Purity	71,85	Autoclaving	VHP	Ergonomic layout to reduce unintended touches	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	7	None	None	None	1	10,26
Contaminated components	Contaminated primary bag stopper track lanes 1-4	Sterility - Purity	20,96	Autoclaving	None	Double-bagging of components	Check-in visual inspection	SOP-instructed	Aseptic technique qualification	6	None	None	None	1	3,49
Contaminated components	Contaminated stopper track lanes 1-4	Sterility - Purity	304,43	Autoclaving	VHP	None	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	6	None	None	None	1	50,74
Contaminated components	Contaminated primary bag stopper track lanes 5-8	Sterility - Purity	20,96	Autoclaving	None	Double-bagging of components	Check-in visual inspection	SOP-instructed	Aseptic technique qualification	6	None	None	None	1	3,49
Contaminated components	Contaminated stopper track lanes 5-8	Sterility - Purity	201,29	Autoclaving	VHP	None	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	6	None	None	None	1	33,55
Contaminated components	Contaminated bonnet stopper hopper	Sterility - Purity	30,40	Autoclaving	None	Redundant critical equipment	Check-in visual inspection (VI)	SOP-instructed	Aseptic and process-specific training	6	None	None	None	1	5,07
Contaminated components	Contaminated stopper hopper	Sterility - Purity	107,22	Autoclaving	VHP	Double-bagging of components	Regular Maintenance (RM)	SOP-instructed	Training on equipment failure SOPs	7	None	None	Contact plates	2	7,66
Contaminated components	Contaminated bonnet	Sterility -				Redundant	Check-in	SOP-	Aseptic and						



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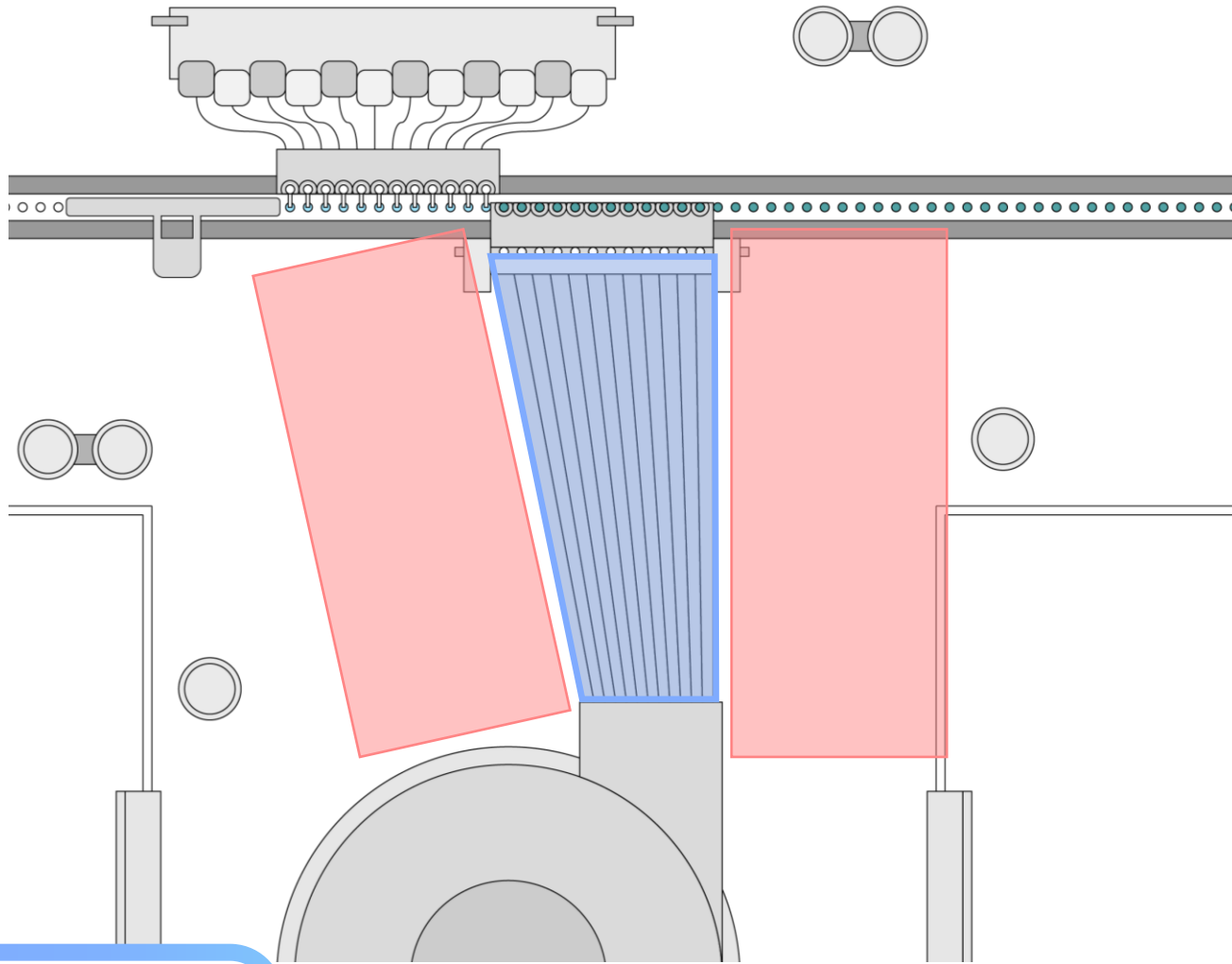
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**Proximity to product**

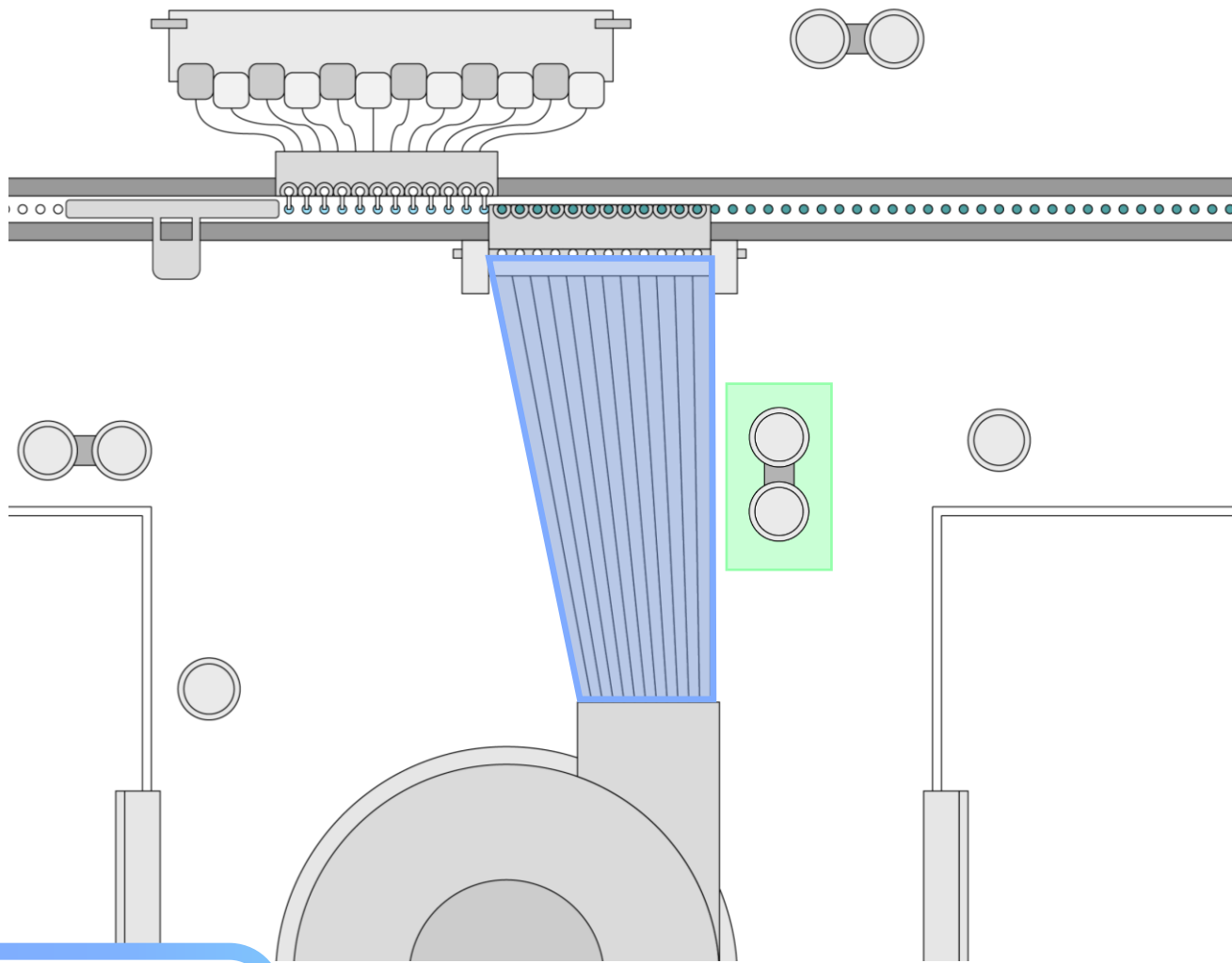
**Manual interventions**

**No monitoring**



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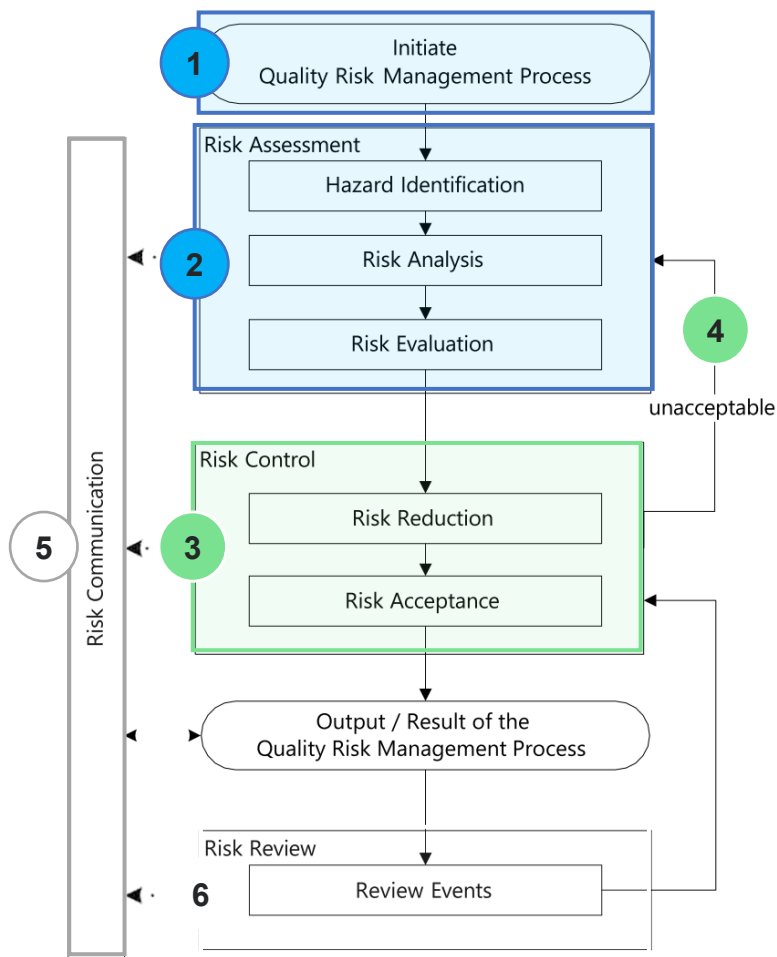
October 8<sup>th</sup> & 9<sup>th</sup>





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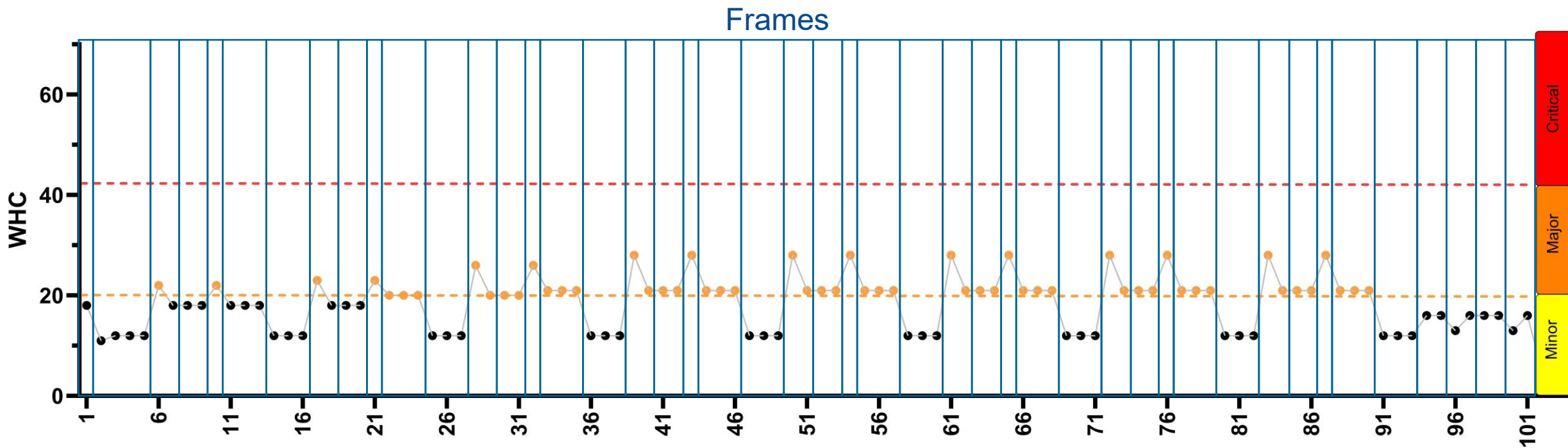
October 8<sup>th</sup> & 9<sup>th</sup>



- (1) Process Mapping
- (2) Risk Assessment
- (3) Process Design
- (4) Risk Control
- (5) Risk Communication



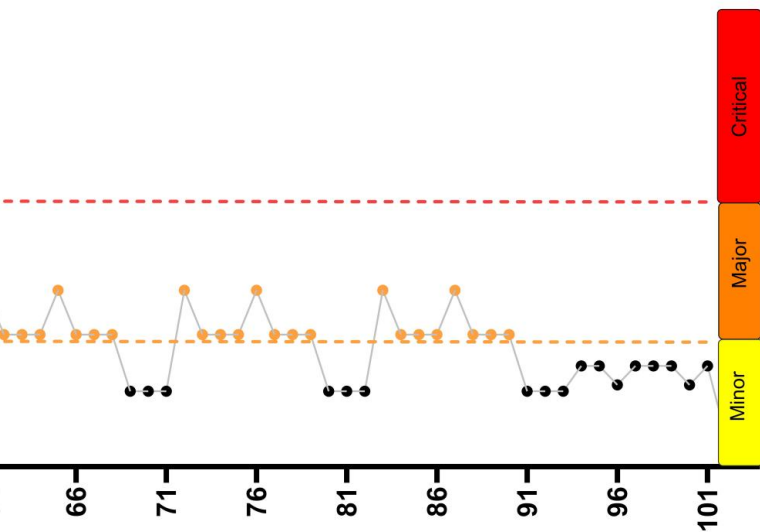
## Auto-generated Process Flow Chart





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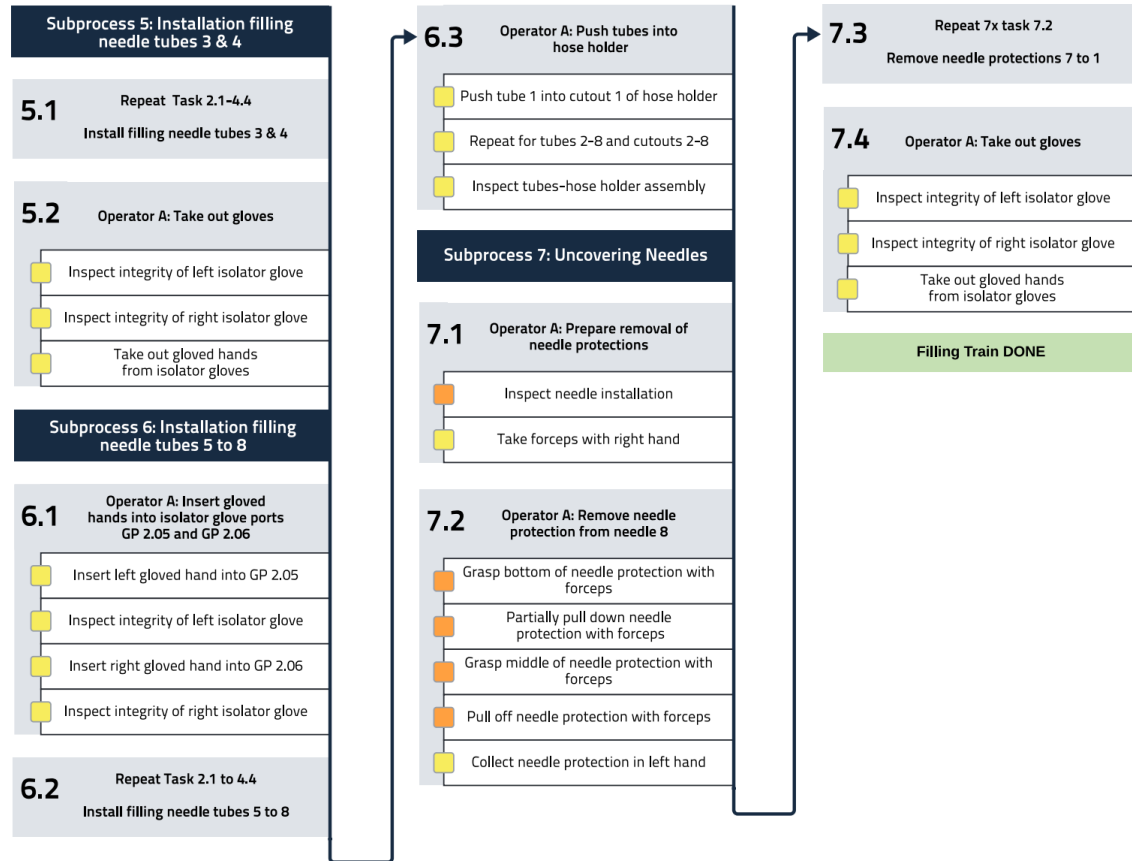


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## PROCESS FLOW CHART





## Frame-by-Frame for Technical Documents **Hazard Flip for Autogenerated Documents**

### Hazard scenario

Opening packaging at the wrong position  
(from the tip side not the plunger)

Not pushing down the plunger



### Correct procedure

Opening packaging at the right position  
(from the plunger side not the tip)

Push down the plunger

Hazard Flip applies a method of inverting defined hazard scenarios to derive their safe procedural counterparts. This approach facilitates the automated generation of procedural documentation.



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Hazard scenarios
Grabbing the wrong needle protection
Touching tip of forceps with hand
Tip of forceps touching isolator
Touching tip of forceps with hand
Damaging tip of filling needle with forceps



Frame	Work Instruction
7.2	<ul style="list-style-type: none"><li>• Needle protections must be removed going from left (needle 8) to right (needle 1)</li><li>• Keep left hand near glove port</li><li>• Approach needle 8 with forceps in right hand from right side under needle holder</li><li>• Grasp needle protection 8 with tip of forceps</li><li>• Don't grasp tip of filling needle</li></ul>

## PROCESS FLOW OF SUBPROCESSES

1	Mixer bag inspection	5	Weighing, dispensing & charging of the API
2	Mixer bag Installation	6	Addition of benzyl alcohol
3	Weighing and dispensing of benzyl alcohol	7	QS Stage
4	Pumping solvent	8	Cleaning of containment isolator

## MATERIALS AND EQUIPMENT



Acube bag



AVAX



Pinch clamp



Mixer



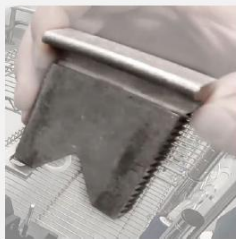
PCS



4inch clamp



Cross frame

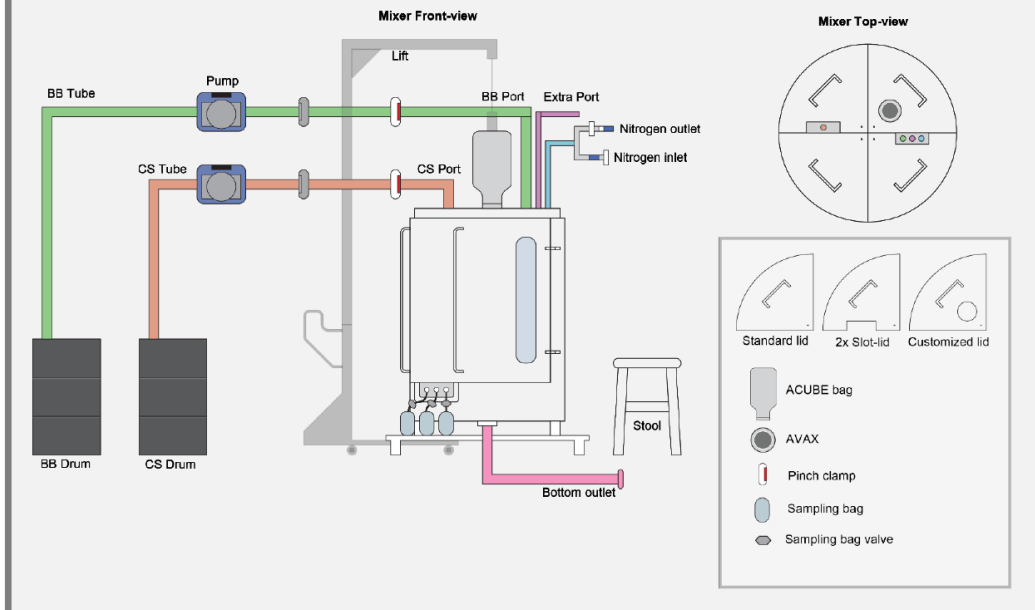


Tube guide in pump

## DEFINITIONS AND ACRONYMS

API	Active Pharmaceutical Ingredient
BB	Benzyl Benzoate
CS	Cottonseed oil
PCS	Process Control System

## PROCESS AREA OVERVIEW



## HIGHEST PROCESS RISKS

**API Handling Risks:** Throughout the process, various manipulations of the API are performed. The critical hazards involve loss of API raw material due to transfer issues, bag ruptures, or AVAX valve failures.

## SUBPROCESS 1: MIXER BAG INSPECTION

### 1.1 OPERATOR A&B: DISINFECT WORKING AREA

FRAMES	WORK INSTRUCTION
1	<p>Operator A&amp;B: Disinfect gloves</p> <ul style="list-style-type: none"><li>Disinfect gloves</li><li>Follow site regulations for appropriate disinfectant</li></ul>
2	<p>Disinfect workbench</p> <ul style="list-style-type: none"><li>Disinfect workbench</li><li>Follow site regulations for appropriate disinfectant</li><li>Don't T&amp;O surface during disinfectant contact time</li></ul>
3	<p>Disinfect secondary packaging</p> <ul style="list-style-type: none"><li>Disinfect whole surfaces of secondary packaging</li><li>Follow site regulations for appropriate disinfectant</li><li>Don't T&amp;O surface during disinfectant contact time</li></ul>



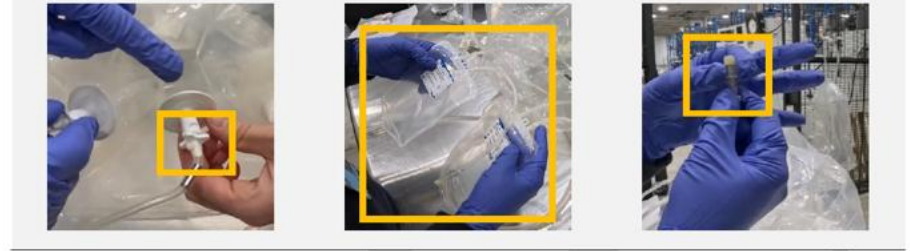
### 1.2 OPERATOR A: OPEN SECONDARY PACKAGING

FRAMES	WORK INSTRUCTION
1	<p>Inspect secondary packaging</p> <ul style="list-style-type: none"><li>Inspect exterior packaging for potential damages including tears, holes, structural integrity or discoloration</li><li>Inspect both sides and corners</li></ul>
2	<p>Take cutter</p> <ul style="list-style-type: none"><li>Take cutter from the handle</li><li>Inspect blade for potential damage</li></ul>
3	<p>Locate primary packaging</p> <ul style="list-style-type: none"><li>Before cutting, find primary packaging border inside</li></ul>

4

Tighten Luer plug

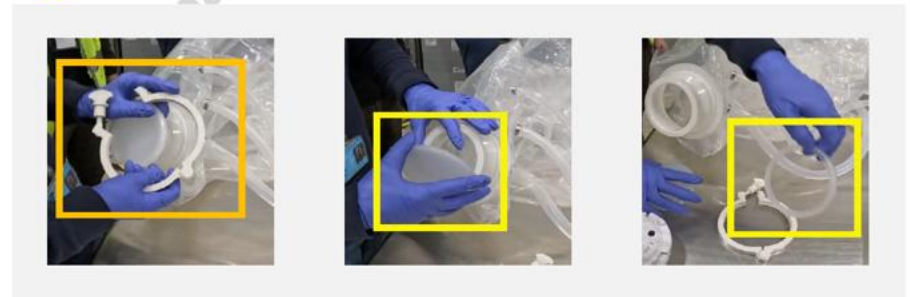
- Fully tighten Luer plug on tip of port connected to sampling bag #1



### 1.13 REPEAT TASK 1.12 FOR SAMPLING BAG #2 AND #3

### 1.14 OPERATOR A: OPEN 4INCH FLANGE

FRAMES	WORK INSTRUCTION
1	<p>Disinfect gloves</p> <ul style="list-style-type: none"><li>Disinfect gloves</li><li>Follow site regulations for appropriate disinfectant</li></ul>
2	<p>Remove 4inch clamp from 4inch flange</p> <ul style="list-style-type: none"><li>Open screw on 4inch clamp</li><li>Open 4inch clamp joint to release 4inch flange</li></ul>
3	<p>Remove blank cap</p> <ul style="list-style-type: none"><li>Remove blank cap from inside of 4inch flange</li></ul>
4	<p>Remove plastic gasket</p> <ul style="list-style-type: none"><li>Remove plastic gasket from inside of 4inch flange</li></ul>

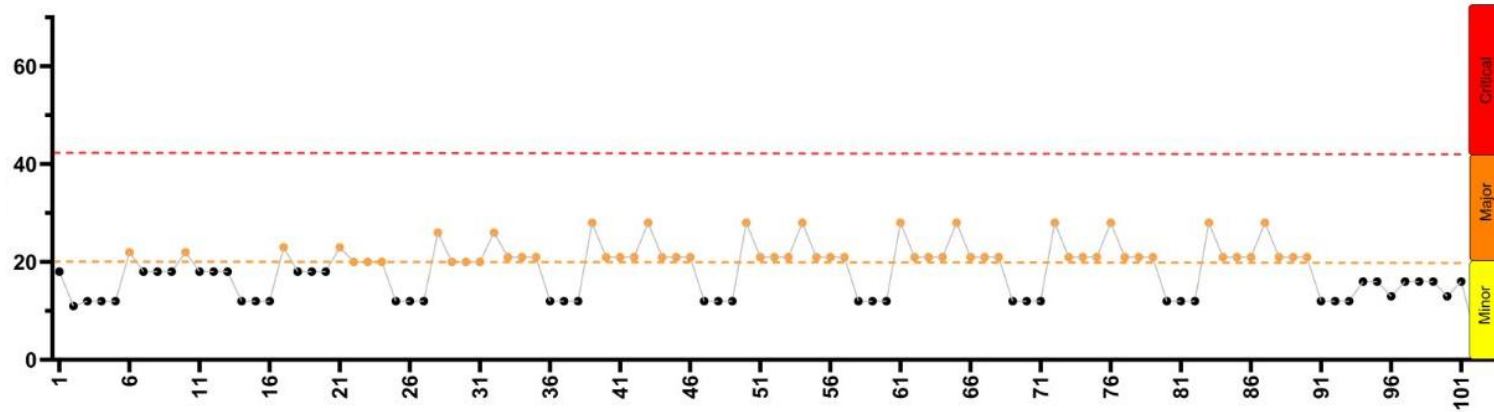
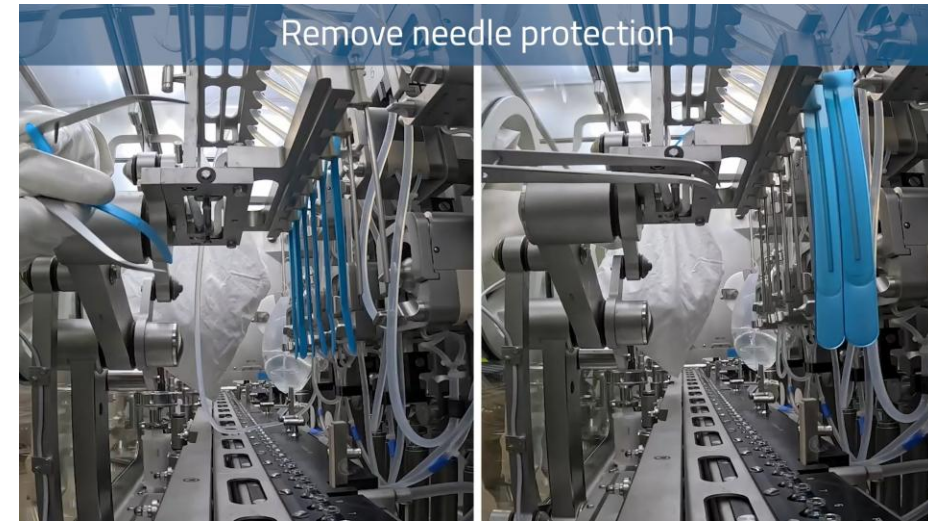


### 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
- Partially pull down needle protection with forceps
- Grasp middle of needle protection with forceps
- Pull off needle protection with forceps
- Collect needle protection in left hand

#### 7.2 OPERATOR A: REMOVE NEEDLE PROTECTION FROM NEEDLE 8

FRAME	VCC	WORK INSTRUCTION - PROCESS TASK (35/37)	OVERSIGHT GUIDELINE		
			EXECUTION	OBSERVATION	MITIGATION
1	Grasp bottom of needle protection 8 with forceps - <b>Don't start with needle protection 1</b>	<ul style="list-style-type: none"> <li>Needle protections must be removed going from left (needle 8) to right (needle 1)</li> <li>Keep left hand near glove port</li> <li>Approach needle 8 with forceps in right hand from right side under needle holder</li> <li>Grasp needle protection 8 with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> <li>Grabbing the wrong needle protection</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Grab needle protection 8</li> </ul>
2	Partially pull-down needle protection with forceps - <b>Don't fully remove protection</b>	<ul style="list-style-type: none"> <li>Use forceps to pull needle protection halfway down going straight down</li> <li>Don't fully remove needle protection or needle might jump out</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Touching tip of forceps</li> <li>Filling needle jumping out</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Push back filling needle reach over from top and document observation</li> </ul>
3	Grasp middle of needle protection with forceps	<ul style="list-style-type: none"> <li>Grasp middle of needle protection with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> </ul>
4	Pull off needle protection with forceps - <b>Don't touch uncovered needle(s) with needle protection</b>	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
5	Collect needle protection in left hand - <b>Don't T&amp;O uncovered needle</b>	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Pass needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



### QRM Report – Dashboard

#### Remove needle protection

**RISK ANALYSIS**

Hazard Cluster Identification

Frame Risk: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101

**Risk reduction**

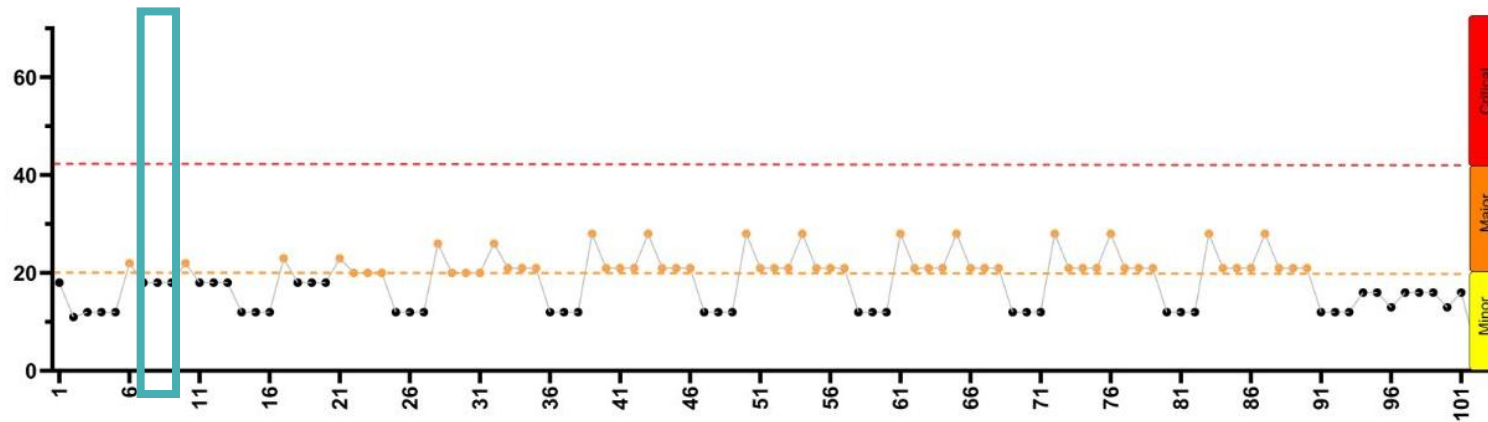
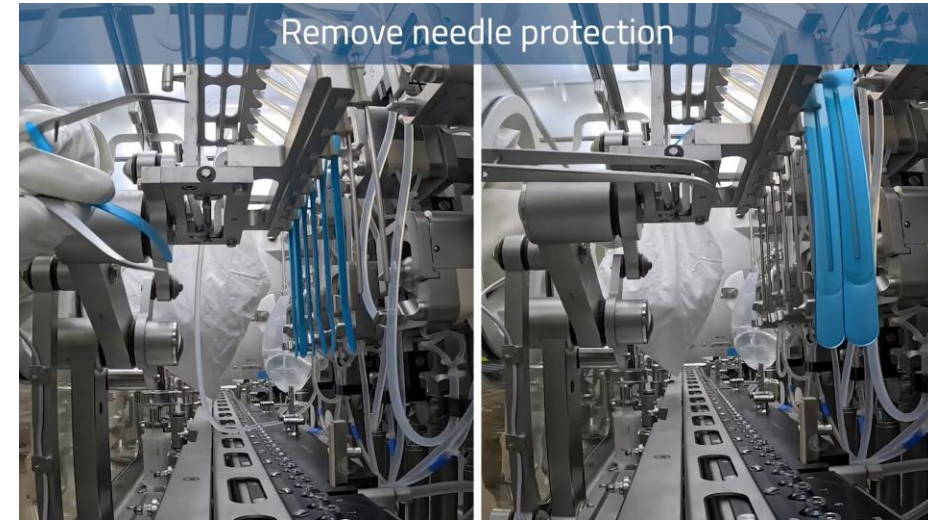
Total hazards	102	75
Minor hazards	33	52
Major hazards	66	23
Critical hazards	3	0
Hazard cluster	1	0

### 7.2 Operator A: Remove needle protection from needle 8

- Grasp bottom of needle protection with forceps
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- Grasp middle of needle protection with forceps
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- Collect needle protection in left hand

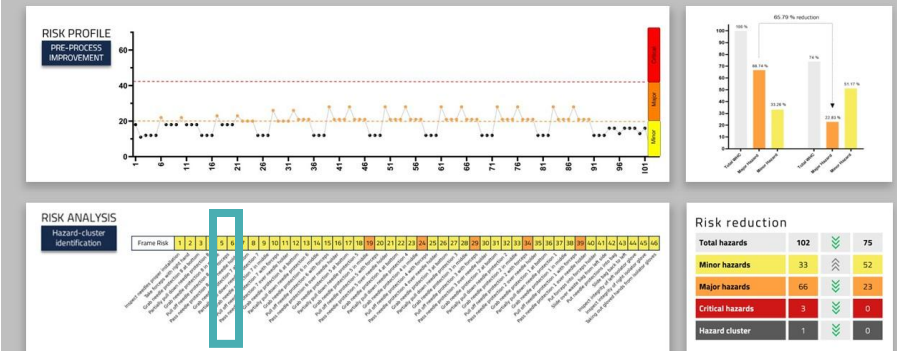
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			EXECUTION	OBSERVATION	MITIGATION
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4	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection straight down</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
5	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Pass needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



### QRM Report – Dashboard

#### Remove needle protection



### 7.2 Operator A: Remove needle protection from needle 8

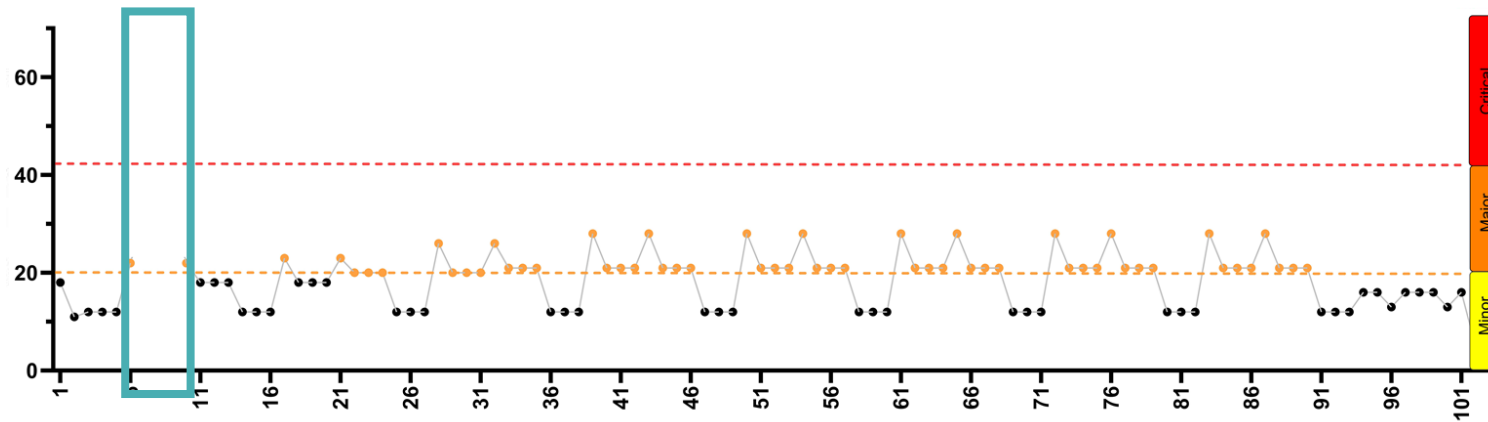
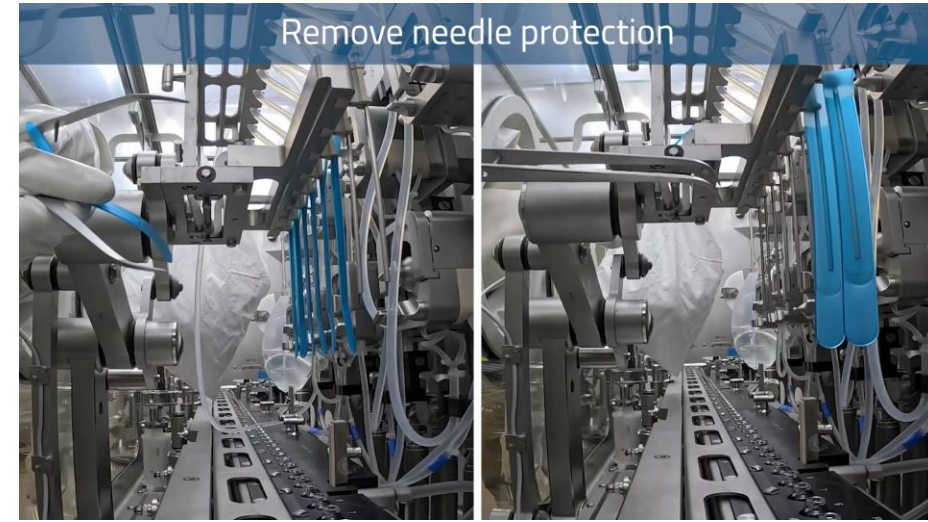
Grasp bottom of needle protection with forceps

Pull off needle protection with forceps

Collect needle protection in left hand

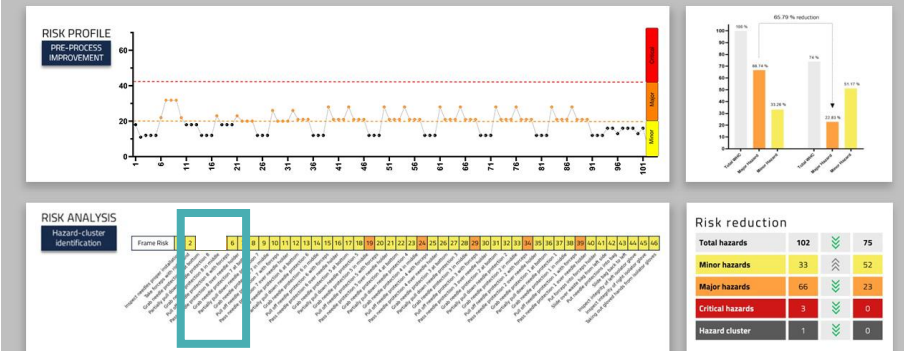
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2	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
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#### Remove needle protection

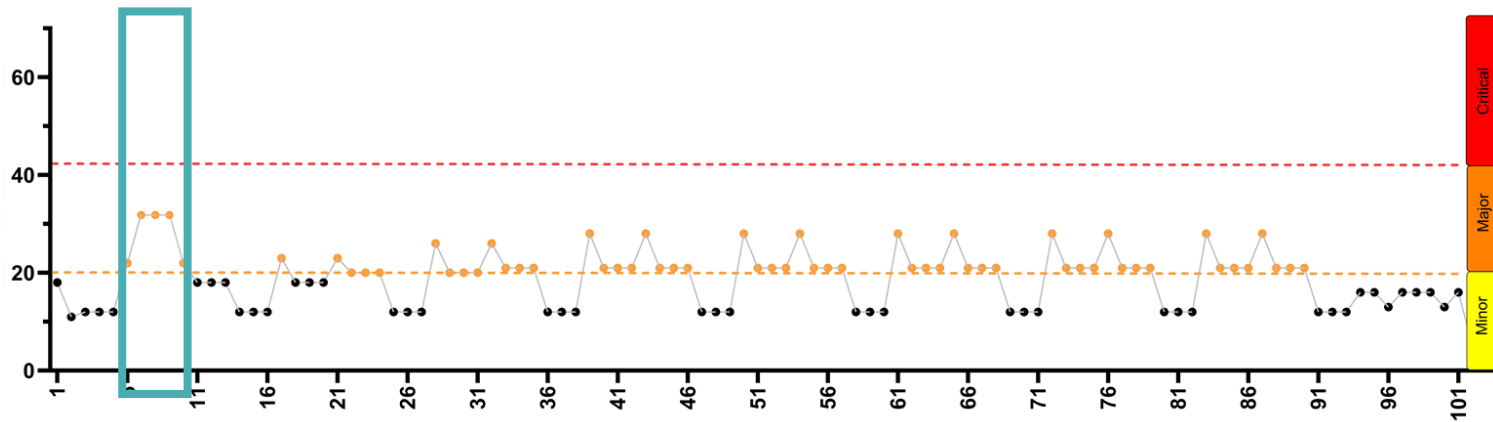
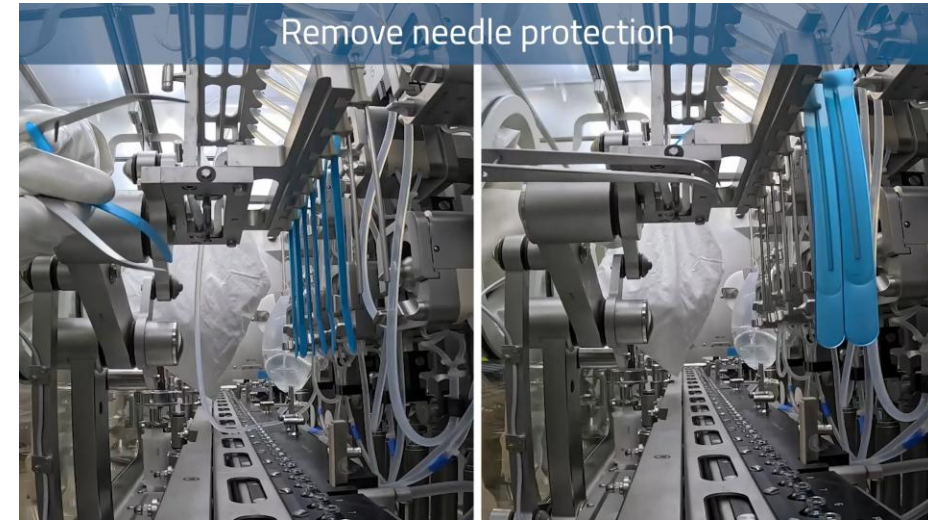


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			EXECUTION	OBSERVATION	MITIGATION
1	Grasp bottom of needle protection 8 with forceps - Don't start with needle protection 1	<ul style="list-style-type: none"> <li>Needle protections must be removed going from left (needle 8) to right (needle 1)</li> <li>Keep left hand near glove port</li> <li>Approach needle 8 with forceps in right hand from right side under needle holder</li> <li>Grasp needle protection 8 with tip of forceps</li> <li>Don't grasp tip of filling needle</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Damaging tip of filling needle with forceps</li> <li>Grabbing the wrong needle protection</li> </ul>	<ul style="list-style-type: none"> <li>Document observation</li> <li>Grab needle protection 8</li> </ul>
2	Pull off needle protection with forceps - Don't touch uncovered needle(s) with needle protection	<ul style="list-style-type: none"> <li>Use forceps to fully remove needle protection</li> <li>Pull needle protection straight down</li> <li>Don't touch uncovered needle(s) with needle protection</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Needle protection touching filling needle 8</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>
3	Collect needle protection in left hand - Don't T&O uncovered needle	<ul style="list-style-type: none"> <li>Withdraw forceps from left to right passing under covered needles</li> <li>Don't T&amp;O uncovered needle</li> <li>Keep left hand near glove port</li> <li>Pass needle protection with forceps to left hand going over needle holder</li> <li>Don't transfer needle protection under needle holder</li> </ul>	NO ERRORS	<ul style="list-style-type: none"> <li>Needle protection falling down</li> <li>Touching or overreaching uncovered needle</li> </ul>	<ul style="list-style-type: none"> <li>Pick up needle protection</li> <li>Document observation</li> </ul>



### QRM Report – Dashboard

#### Remove needle protection

